EXHIBIT N

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP., MDL NO.: 2326

PELVIC REPAIR SYSTEM

PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

Chapa v. Boston Scientific Corporation	2:13-cv-17511
Fisher v. Boston Scientific Corporation	2:13-cv-29324
Flandro v. Boston Scientific Corporation	2:13-cv-17027

Toronto, Ontario, Canada

Wednesday, December 17, 2014

VOLUME I

Videotaped Deposition of VLADIMIR IAKOVLEV, M.D., a witness herein, called for examination by counsel for the Defendants in the above-mentioned matter, the witness having been affirmed, taken at the offices of Neesons Reporting, 141 Adelaide Street West, Toronto, Ontario, at 9:11 a.m., on Wednesday, December 17, 2014, and the proceedings being taken down by Stenotype and transcribed by JUDITH M. CAPUTO, RPR, CSR, CRR.

THIS DOCUMENT RELATES TO: (Cont'd)

Fleming v. Boston Scientific Corporation 2:12-cv-05131
Franco v. Boston Scientific Corporation 2:12-cv-07248
Hanson v. Boston Scientific Corporation 2:13-cv-10653
Hoffman v. Boston Scientific Corporation 2:12-cv-04433
Howard v. Boston Scientific Corporation 2:12-cv-04145
Kilgore v. Boston Scientific Corporation 2:13-cv-09171
Parker v. Boston Scientific Corporation 2:12-cv-01243
Reynolds v. Boston Scientific Corporation 2:12-cv-09934
Robbins v. Boston Scientific Corporation 2:12-cv-01413
Tame v. Boston Scientific Corporation 2:13-cv-01059
Watanabe v. Boston Scientific Corporation 2:13-cv-12227

A P P E A R A N C E S:

ON BEHALF OF THE PLAINTIFFS:
BY: JONATHAN D. ORENT, ESQ.
Motley Rice, LLC
321 South Main Street, 2nd Floor
Providence, Rhode Island 02903
401.457.7723

A P P E A R A N C E S:

ON BEHALF OF THE PLAINTIFFS:
BY: ALAN S. LAZAR, ESQ.
Marlin Saltzman, LLP
29229 Canwood Street, Suite 208
Agoura Hills, California 91301
818.991.8080

ON BEHALF OF THE PLAINTIFFS:
BY: NATHAN C. BESS, ESQ.
Aylstock, Witkin, Kreis & Overholtz
17 East Main Street, Suite 200
Pensacola, Florida 32502
850.202.1010

ON BEHALF OF THE PLAINTIFFS:
BY: KATY KROTTINGER, ESQ.
The Monsour Law Firm
404 North Green Street
Longview, Texas 75606
903.758.5757

A P P E A R A N C E S: (Cont'd)

ON BEHALF OF THE PLAINTIFFS:
BY: CRAIG EILAND, ESQ.
Law Offices of Craig Eiland
2211 The Strand, Suite 201
Galveston, Texas 77550
409.763.3260

ON BEHALF OF THE DEFENDANTS:
BY: ADRIENNE L. BYARD, ESQ.
Shook, Hardy & Bacon, LLP
2555 Grand Boulevard
Kansas City, Missouri 64108
816.474.6550

ALSO PRESENT:
DENNIS COSTIGAN, Motley Rice LLC

I N D E X

INDEX OF EXHIBITS

1198: International Scholarly and Scientific Research & Innovation, 2014, Publication entitled, "Pathology of Explanted Transvaginal Meshes," by Dr. V. Iakovlev, Dr. E. T. Carey and Dr. J. Steege. 156

1199: Abstract entitled, "Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh is Not Inert," by Dr. V. Iakovlev, Dr. G. Mekel and Dr. J. Blaivas. 186

1201: Abstract entitled, "In-vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades," by Dr. V. Iakovlev, Dr. S. Guelcher, Dr. R. Bendavid. 207

-- Upon commencing at 9:11 a.m.

THE VIDEOGRAPHER: Good morning. We are now on the record. My name is Peter Goodale, certified legal videographer for Golkow Technologies.

Today's date is December 17, 2014, and the time on the video monitor is 9:11 a.m.

This video deposition is being held in Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of West Virginia, Charleston Division, MDL No. 2326.

The deponent is Dr. Vladimir Iakovlev. Counsel, please identify yourselves and state who you represent.

MR. ORENT: Jonathan Orent for the Plaintiffs.

MR. LAZAR: Alan Lazar for the Plaintiffs.

MR. BESS: Nathan Bess, also for the Plaintiffs.

MS. KROTTINGER: Katy Krottinger for the Plaintiffs.

MS. BYARD: And Adrienne Byard for Defendant, Boston Scientific.

MR. EILAND: Craig Eiland for the Plaintiffs.

THE VIDEOGRAPHER: Thank you.

The court reporter is Judy Caputo, CSR, and who will now swear in or affirm the witness. Whereupon,

VLADIMIR IAKOVLEV, M.D.,

called for examination by counsel for Defendants and having been affirmed by me, was examined and testified as follows:

DIRECT EXAMINATION BY MS. BYARD:

Q. Dr. Iakovlev, it's very nice to see you again. You'll recall I'm Adrienne Byard. I think the last time we had the opportunity to talk was in January of 2014, when I took your deposition here in Toronto. Do you remember that deposition?

A. Yes, I do.

Q. And since that time you've been deposed again; correct?

A. By Boston Scientific, yes.

Q. And also by other mesh manufacturers, right?

A. Yes, that's correct.

Q. Okay. And you've also had the opportunity to testify at some trials; correct?

A. Yes.

Q. Let's work forwards in time.

So from January 2014, when I took your deposition here in Toronto, when was your next deposition?

A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March --

Q. Let me stop you there, if you don't mind. Were those in an AMS matter?

A. Yes.

Q. And just one, one case, right?

A. What do you mean "one case"?

Q. Was it just -- were you just looking at pathological specimens for a single case, or were your opinions applying across AMS cases; if you know?

A. There were a number of cases.

Q. Okay. And then when was your next deposition?

A. From February 4th?

Q. Yes. February and March for AMS, and then when was the next one?

A. Then there was one for Ethicon in April.
Q. Okay.
A. But that's not a memory test. The recent depositions is provided on the flash drive for you.
Q. Okay. So you've brought some materials with you here today through counsel in response to our request. Is that what you're saying?
A. That's correct.
Q. Okay. And we'll go ahead and mark as 1195, the Notice of Deposition. I'll pass a copy of that to you.
EXHIBIT NO. 1195: Notice of Videotaped Deposition Duces Tecum of Dr. Vladimir Iakovlev.
BY MS. BYARD:
Q. Is this deposition notice, or one similar to it, familiar to you, sir?
A. Yes.
Q. And did you bring documents responsive to our request through counsel?
A. Yes.
Q. What were the documents, as far as

you understand it, that were being brought here today in response to our request?
A. Medical records I reviewed for the Plaintiffs. My publications, billing I produced for the Plaintiffs, which were identified in this notice.
Q. Okay.
A. For whatever reason, there is no list here. It looks different than what I received.
Q. Right. The list you saw, and I'll just show you this -- we're not going to mark it at this point -- but it was a longer list like this, right?
A. Yes. That looks more familiar than this.
Q. Okay. And so you brought the billing that pertained to those women's cases, right?
A. Um-hum.
Q. Okay.
A. Yes.
Q. Now, when you say "obligations," what do you mean by that?
A. What do you mean?

Q. You said "my obligations"?
A. No, no, I didn't say that.
Q. Oh, really? Okay, I missed it then. Somewhere between "medical records reviewed for Plaintiffs" and the "billing for Plaintiffs" --
MR. ORENT: He said "publications."
BY MS. BYARD:
Q. "Publications." Publications, thank you so much.
You'll remember the rules of the deposition, I'm sure, that if there are times when we don't understand each other, I'll ask for clarification and I'll ask that you do the same; all right?
A. Sure.
Q. If you don't ask for clarification, I'll assume you understood me, okay?
A. (Witness nods).
Q. Is that fair?
A. Yes, that's fair.
Q. Very good.
What else was, besides your publications, the medical records you reviewed for Plaintiffs, and the billings for Plaintiffs, is on that thumb drive, so far as you know?

A. The list of testimonies I gave.
Q. Okay.
A. My current CV.
Q. You don't have a paper copy of that that I could review and go over with you now of any of those materials?
A. No, I didn't bring them. I tried to save trees.
Q. Okay. Well, we'll take that up on a break.
I want to return to this list of depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given depositions in any cases involving any other manufacturers of transvaginal mesh?
A. Yes.
Q. Okay. Which others?
A. Bard.
Q. When was that deposition?
A. Let me turn it up. The deposition for Bard was in November.
Q. November. Now you've also testified at some trials; correct?
A. That's correct.
Q. What trials have you testified at

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and when were they?
A. Both were for Boston Scientific devices. One trial was in August for Ms. Cardenas and the other one was in Miami for Ms. Eghanayem and other patients.
Q. Going back to depositions, you also had -- besides the time that I took your deposition in January with Ms. Weiler for Boston Scientific, you also had a deposition in July, where you covered, specifically, the Cardenas and the Eghanayem matters, right?
A. That's correct.
Q. So all told, you've been deposed once in the Boston Scientific MDL; once for two specific cases in the Boston Scientific MDL; once for Ethicon --
A. Twice.
Q. Twice for Ethicon. Then a deposition for Bard?
A. Twice for Bard.
Q. Twice for Bard. And so we're in the neighborhood of six or seven depositions?
A. That's correct.
Q. And two trials?
A. That's correct.

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Q. Because we've already covered so many of your opinions with you in these other depositions and at trials, I'm not going to rehash a bunch of old ground with you.
I'd like to specifically cover with you today, your deposition for these wave cases, this general report that you've authored. It's roughly the 93-page report that was submitted in the wave cases, all right?
And then I'd also like to cover with you some of the updates to your opinions, if any, okay, sir?
A. (Witness nods.)
Q. Has your opinion across these depositions and trials been basically the same? And by that I mean, that the tissue response that you see the polypropylene mesh is essentially similar across all the various manufacturers?
MR. ORENT: Objection.
THE WITNESS: Yes, to a degree. I learn a little bit more after examining more specimens, more details. But basic principles remain the same.
BY MS. BYARD:
Q. Have you in your observations of

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tissue and mesh samples, observed any differences that you believe would increase or decrease the risk of clinical complications in women, depending on the type of mesh that is used?
MR. ORENT: Objection.
THE WITNESS: Define "type." Different manufacturer, different device, different knit pattern? I mean, what, what exactly --
BY MS. BYARD:
Q. Any of those are fine. It's an open-ended question.
A. In some lightweighter meshes, there is more inclusion of normal tissue into the pores. The difference is not drastic, but there is -- at the same time, these lightweight meshes fold easier, so it defeats the purpose of the design.
But theoretically, they're flat. They would behave better than those more heavier with less pores. I mean, there are drawbacks and cons and pros of this, but the design behaves slightly differently than other designs -- than heavier weight designs. That's what I can say.
Q. So at this point, based on your observations to date, you're not in a position to

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say that those designs are safer or would minimize the risk of clinical complications in women, right?
MR. ORENT: Objection.
THE WITNESS: Not to a noticeable degree.
BY MS. BYARD:
Q. Okay.
A. To detectable degree.
I see they behave differently, the tissue reacts differently. But all of them came to me because of complications.
Q. Right.
A. So I ended up with specimens which are excised complications. Therefore, complications occurred in those.
Q. And I believe you noted in one of your original reports, that there's mesh that has tangs and mesh that doesn't have tangs, comparing Boston Scientific mesh either between products or Boston Scientific mesh to other products; do you recall that distinction?
A. Yes, there is distinction. I mean, some are tanged; heat treated them in slings, but they're not treated along all lengths. Some are shorter segment.
So it also behaves somewhat differently.

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But the end result was they became excised, they were problematic.

Q. So similarly, you're not in a position today, based on your observations to date, to testify that the tissue response to the de-tanged mesh versus tanged mesh, is better or worse in terms of its likelihood of causing complications in women, right?

MR. ORENT: Objection.

THE WITNESS: That is difficult question. I mean, you're asking likelihood. This would be more of a clinical question, and to be a clinical trial, larger trial.

I can tell you that there is a different tissue reaction. And I can tell you that my specimens came to me because patients experienced complications.

But I would not be able to give you a statement of what's the percentage of improvement or, or lack of improvement.

BY MS. BYARD:

Q. And you wouldn't be able to say that to a reasonable degree of certainty, right?

MR. ORENT: Objection.

THE WITNESS: I just wouldn't be able

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to say that. And these factors, the efficacy, it was a clinical question that had to be a long-term clinical study.

BY MS. BYARD:

Q. Okay. What were the -- you said there are some differences. What were the tissue responses that you've seen that are different between tanged and de-tanged mesh?

A. If it's tanged, the edges don't curl as much. So if it's a sling, I can see clearer difference. When it gets excised, the heat-treated portion doesn't curl. But then there is a sharp transition into non-heat-treated portions, and they curl.

So if those slings were not -- I mean, original slings were not heat-treated, so the whole length is curled into a rope. But if there is section is treated, that section doesn't curl, but the ends curl. So I can see the difference. But the design failed in one way or another.

Q. And so a distinction I might try and make throughout the day, and I want to make sure it's accurate. You're talking about the shape of the mesh itself, right, if it curls --

A. Shape before insertion, or shape

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after excision, or during in vivo?

Q. Sure. So you're talking about the shape after excision; correct?

A. That's correct.

Q. Okay. And when you look at the shape after excision, you're not able to say with certainty, what the shape of the mesh was in vivo, typically, unless it's completely encased in scar tissue, right?

MR. ORENT: Objection.

THE WITNESS: That's not correct statement. I can find features which will give me indication what was shape in vivo. I am able to say what was shape in vivo.

BY MS. BYARD:

Q. Let's take that up in a little bit, if you don't mind.

Returning, though, to your statement that the heat-treated edges don't curl, was that your basic observation?

A. Generally, yes.

Q. Okay. And so the de-tanged sub-urethral portion of the Boston Scientific mesh slings had a lesser propensity to curl?

A. That's correct.

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MR. ORENT: Objection.

BY MS. BYARD:

Q. In terms of the tissue response, the amount of inflammation that you've seen was the same between de-tanged and non-de-tanged mesh, though?

A. It's exactly the same. There is no difference. No detectable difference.

Q. And you make a distinction between an inflammatory response that you see under a microscope and a foreign body reaction; correct?

A. A foreign body reaction is an inflammatory response. I don't make a distinction.

Q. Okay.

A. I make distinction between types of inflammatory reaction.

Q. In particular, whether or not there is a presence of multinucleated cells or giant cells?

A. These are just microfibers who decided to become multinucleated. So there is no difference between multinucleated microphage and single nucleated microphage. Functionally, genetically, they're all the same.

Q. Does it tell you whether or not

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the inflammatory reaction is in response to a foreign body, though, depending on the type of macrophage?

A. No. All macrophage is a reaction to foreign body.

Q. Okay.

A. If there is a foreign body, and there are macrophages, they're reacting. Because, generally, the foreign body or granulomatous reaction is defined as epithelioid histiocytes or macrophages.

Q. So if my question were whether you had seen any difference in the foreign body reaction between de-tanged and tanged meshes, your answer would be the same; wouldn't it? No, you didn't see a difference?

MR. ORENT: Objection. Asked and answered.

THE WITNESS: That's correct. I did not see the difference.

BY MS. BYARD:

Q. Okay. I want to look at your billing records once we have copies of them, but do you have a number in mind of all told how much you've been paid by Plaintiffs in the mesh

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litigation for your expert work against Boston Scientific?

A. It's hard to say now, because I don't keep that exact records, really, I'm so busy.

Last year my income tax return was $24,000 from depositions and statements. This year it's larger. I don't know how much larger.

Q. Is it two times larger?

MR. ORENT: Objection.

THE WITNESS: Possibly.

BY MS. BYARD:

Q. Could it be three times larger?

MR. ORENT: Objection.

THE WITNESS: I don't want to guess.

BY MS. BYARD:

Q. What would you need to do to calculate for me how much money you've been paid by plaintiffs for acting as an expert against mesh manufacturers?

A. I would have to --

MR. ORENT: Objection. Form.

THE WITNESS: I would have to complete billing, which I have not completed yet. I mean, this is a long list, it takes a long time to produce all of this, and I just didn't have time to

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complete the billing.

BY MS. BYARD:

Q. But you will by the time you file your taxes?

A. Yes.

Q. And when do you anticipate doing that?

A. Next spring.

Q. Did you do anything to prepare for your deposition today?

A. I prepared documents for you on the flash drive.

Q. Did you meet with counsel to review documents?

A. Yes, we met yesterday.

Q. Have you prepared by phone for your deposition here today?

A. No.

Q. How long did you meet yesterday?

A. A couple of hours.

Q. And did you review any materials that weren't provided on that flash drive?

A. No, we just went through whatever was on the flash drive and my reports.

Q. Do you intend to bill for the time

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that you spent yesterday with counsel?

A. Yes.

Q. How much is your rate now?

A. 475.

Q. It's gone up.

A. I published, so I don't think it's too high. I mean, I see some reports which are much higher.

Q. So you hadn't worked on mesh before as a subject area or a material before 2013, right?

A. 2012.

Q. 2012?

A. Yeah, first time I saw it -- became involved in this was end of 2012.

Q. And that was your work with Dr. Bendavid on hernia meshes; correct?

A. That's correct.

Q. And then in 2013 you were approached by Plaintiffs' attorneys in litigation and began working on transvaginal mesh as opposed to hernia mesh; correct?

MR. ORENT: Objection.

THE WITNESS: I don't know who approached me first. So I don't remember now what

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was my first transvaginal specimen. Probably an attorney, probably Dr. Thomson asked me to look at it. Maybe, maybe not. I don't know, I don't remember now.

BY MS. BYARD:

Q. Okay. And originally your rate was $400, and now it's $475, right?

A. That's correct.

Q. And why did you increase your rate?

A. As I said, I published, I'm more experienced. It wouldn't be unfair, because when I started I had no experience in litigation cases.

Q. So since beginning work on transvaginal mesh matters in 2013, and now sitting here today at the end of 2014, you've now published articles on the subjects of this litigation; correct?

A. No, this is not correct. I didn't publish on the subject of litigation. I published on my research, on topics of surgical polypropylene meshes.

Q. Based on your review of specimens provided to you by Plaintiffs' attorneys in litigation?

MR. ORENT: Objection.

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THE WITNESS: Most publications actually are based on hernia meshes, which were coming from just regular patients. I examined more specimens for litigation, but publications are mostly based on that.

BY MS. BYARD:

Q. Okay. We can take a look at those articles. Before we do, though, let's mark your report as 1196.

MS. BYARD: Do you need a copy, John?

MR. ORENT: Yeah, we'll take copies of everything, just position them on my list here somewhere.

EXHIBIT NO. 1196: General Expert Report of Dr. Vladimir Iakovlev dated November 10, 2014.

BY MS. BYARD:

Q. Doctor, do you recognize 1196?

A. Strange, 1196. Where are 1195?

Q. Sorry, that's just the exhibit number. Do you recognize this document?

A. Yes, I do recognize this. It's just, exhibit usually starts with number one, but now it's throwing me.

Q. I know, I know. You and me both.

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You recognize it, though?

A. Yes, this is my document.

Q. And if you flip into the document, you'll see your signature on it? Hopefully.

MR. ORENT: Page 65.

THE WITNESS: Yes, I do.

BY MS. BYARD:

Q. What date did you sign this report?

A. November 10th.

Q. When did you start working on it?

A. This is a general report, so essentially, this has been transformed original report. We discussed in January, so it just was modified several times, reformatted and new images were inserted so...

If you ask me when I started working on this, it would be probably two thousand and -- early -- late 2013.

Q. Okay. Have you issued similar reports, reports in formatting similar to this one in the other mesh manufacturers' cases?

A. Yes. Usually we keep the same format, general report and case-specific reports.

Q. Visually, this report appears different than the report I originally deposed you

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about in January of 2014. Do you agree with me about that?

A. Yes. This is more structured. Because I understood that, medically, though moderate, a little bit difference, so it's not a guide for -- my report shouldn't be a guide for a clinician. It should be more of a legal document.

Q. And I understand that you've continually built on your base knowledge in coming at what we have here as a final work product. But when was the transition made between the format of a report that we looked at in January of 2014 to what we see here today?

MR. ORENT: Objection.

THE WITNESS: In October or November. Because some of the supplied reports, they had older general part, older format. And some had -- so it was somewhere in -- during my work on this report. I had to streamline it. This is a huge number, a huge amount of work. I had to streamline it and kind of organize it in a way that it would be easier to produce this large number.

BY MS. BYARD:

Q. And that was one of my questions for you. I don't want to get into the

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case-specific reports today, but some of them revert to the earlier format that you used, right?
A. Yes.
Q. But the exhibit that we're looking at, 1196, this reflects the most -- I guess your most distilled version of your opinions in this litigation; is that fair?
A. I don't know about distilled, but it's most updated version, most recent.
Q. So if we wanted to talk about your current opinions, it would be better for us to work off of 1196 than the version that I deposed you about in January of 2014, right?
A. Yes, it would be easier.
Q. Okay. Notwithstanding the fact that that older version appears inserted in some of these case-specific reports that we'll talk about tomorrow, right?
A. That's correct.
Q. Okay, good. Turning to your report, we start off with your qualifications. Are you with me?
A. Yes, I am.
Q. Have there been -- and then we have attached as an exhibit to your report, we have

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your CV; true?
A. Yes, I saw it.
Q. I think it's Exhibit A.
Apart from the publications that I'll talk about here in a moment as they come up in the report, have there been any other updates to your CV or your qualifications?
A. Publications, presentations, abstracts, posters, that's main things, nothing else.
Q. Okay.
A. I'm still working in the same place.
Q. Same place, same title?
A. (Witness nods.)
Q. Very good. And if we go further into your report, you have a section -- it's the second paragraph on page 2. It's the first full paragraph.
Here where you're talking about the research that you started with Dr. Bendavid, you mention in the last sentence that:
"Previous studies in manufacturers' testing have been concentrated on experimental modeling in animals and controlled

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testing in a laboratory environment."
Did I read that correctly?
A. Yes, that's correct.
Q. I believe we previously established, but I wanted to make sure in light of this language, that you haven't reviewed any of Boston Scientific's internal testing?
A. No, not specifically Boston Scientific.
Q. Okay. And have you reviewed any of Boston Scientific's biocompatibility testing?
A. No, not internally.
Q. Have you reviewed any of Boston Scientific's animal testing?
A. As I said, I had no access to specifically internal documents of Boston Scientific.
Q. Would it interest you, as a pathologist, to see what Boston Scientific's animal testing revealed about the tissue response to its products?
A. Yes, it would be interesting.
Q. Is that anything that you requested from the Plaintiffs' counsel?
MR. ORENT: Objection.
THE WITNESS: It didn't occur to me

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that you would provide it.
BY MS. BYARD:
Q. And similarly, you haven't done a review of the literature for clinical studies conducted on Boston Scientific's products, right?
MR. ORENT: Objection.
THE WITNESS: Repeat --
MR. ORENT: Hold on one second.
Do you mean "randomized control"? Because the term "study" has a very specific meaning in science.
MS. BYARD: Counsel, please don't coach the witness with your objections.
MR. ORENT: No. I'm asking you to clarify the question.
BY MS. BYARD:
Q. Clinical studies, studies in humans.
What does "clinical studies" mean to you, sir?
A. Please repeat the first question.
Q. Sure. What does clinical -- what does the term --
A. No, no, previous question.
Q. No, that's okay. It's my

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deposition. What is --
MR. ORENT: Are you withdrawing the prior question?
MS. BYARD: Yes, I'll withdraw that.
BY MS. BYARD:
Q. What does the term "clinical studies" mean to you as opposed to "preclinical studies"?
A. Clinical studies, when it's experimentational testing is done on patients.
Q. Okay. Have you reviewed any of the clinical studies, so testing on humans, of Boston Scientific's products?
MR. ORENT: Objection.
THE WITNESS: I have reviewed published literature from clinical studies, including Boston Scientific. Usually it's a mix, it's not a separate -- sometimes it's a separate device, but mostly it's a mix.
BY MS. BYARD:
Q. Okay. So you couldn't say, you couldn't sit here today and testify that you've reviewed all 25-plus Obtryx studies, for instance; could you?
MR. ORENT: Objection. Foundation.

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I think the record speaks to the fact there aren't 25 studies in Obtryx.
MS. BYARD: Counsel, please, make a form objection.
THE WITNESS: I have a large hard drive filled with publications which I reviewed. I don't remember how many of those were Obtryx and so -- but I can tell you that I read a lot of clinical studies.
BY MS. BYARD:
Q. Okay. I want to turn to the next paragraph here in this preface to your report, which talks about your review of polypropylene mesh explants. Are you with me?
A. Yes.
Q. And you reference, "now having approximately 120 samples being transvaginal mesh explants."
A. This number is probably higher now, something like 150.
Q. Is there a way that you track this number?
A. When I have time, I sit and then start putting them in spreadsheet. But I haven't done it for last two months.

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Q. Okay.
A. I have piles sitting on my desk now to sort out, maybe Christmastime.
Q. Okay. And so when was the last time you updated this spreadsheet?
A. Late August, early September, somewhere in that time. It was slow time, so I could, could do that.
MR. ORENT: Vladimir, can you just keep your voice up.
THE WITNESS: Sure, yeah. Just remind me.
BY MS. BYARD:
Q. I don't know that we have a copy of the spreadsheet, so that's something that I would request.
A. I provided it in July. I don't remember if I updated since then, but it could be a small update.
Q. Okay.
A. But you received a copy in July. I think in July it was 97 transvaginal cases.
Q. So I don't, though, have a spreadsheet that would reflect this 120 number of samples that appears here in your report, right?

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A. I'm not sure if it exists. And, yes, I counted those 97. I know the number because I could count them quickly, but they are not entered in the spreadsheet.
Q. Okay. I guess I should back up for a second.
Are you fully prepared to discuss all the opinions that are set forth in your report today?
A. Yes.
Q. Okay. And have you seen everything that you need to see, to offer the opinions that are set forth here in 1196?
A. Yes.
Q. Okay. And do you have any additional info, information, at this time that would change the opinions that are reflected here in Exhibit 1196?
A. No.
Q. Okay. And did your report include all of the opinions, the basis and the reasons for your opinions that you intend to offer in trial on these matters?
A. No. Because basis of my opinions is my career, my knowledge and everything. It

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cannot fit in this report. It's just a summary.
Q. Are all of the opinions that you intend to offer at trial set forth in this report, Exhibit 1196?
A. As I said, there's a summary, yes.
Q. And you understand that if there are updates to this information, that you'll supplement this through counsel, right?
MR. ORENT: Objection.
THE WITNESS: That's correct.
BY MS. BYARD:
Q. Of these 120 samples that -- of transvaginal mesh that you had at least as of the date that you authored your report and signed it, how many of those had come to you through Plaintiffs' attorneys?
A. Ratio is somewhat close to 70 percent. Again, it's approximate ratio.
Q. Previously when we've deposed you, you've testified that you didn't know how the Plaintiffs' attorneys selected the specimens that they sent to you; do you recall that?
A. I don't know the specific details, but I think it's an irrelevant question, because nobody knows what's in the specimen unless you look

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in the microscope. So they selected it blindly.
MS. BYARD: Object and move to strike.
BY MS. BYARD:
Q. Do you recall having testified before that you didn't know how the Plaintiffs' attorneys selected the specimens that they sent to you?
MR. ORENT: Wait a minute. Hold on.
He's entitled to a full answer, so we would oppose any motion to strike.
Go ahead and answer to the extent that you need to, to make sure that you're offering a full testimony, full response to the question.
BY MS. BYARD:
Q. My question is whether you testified before that you didn't know how Plaintiffs' attorneys selected the specimens that they gave to you?
MR. ORENT: Objection.
THE WITNESS: What was their methodology? I don't know.
But as I said, they selected it blindly because they couldn't see what's in the specimen. There's no way of seeing -- I don't know what I'm going to find in a specimen before I cross it.

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BY MS. BYARD:
Q. Okay. I'd like to look with you, and I'll represent to you that these are reports that my expert, Dr. Steven Badylak, put together based on specimens that he reviewed.
And the first is for a woman named Ellen Hoffman; another is for a woman named Connie Bennett; and another is for a woman named Deborah Kilgore. If you wouldn't mind taking the time to just briefly review those.
MR. ORENT: Let me see those.
THE WITNESS: They look awfully short in comparison to mine.
MS. BYARD: There was no question pending, sir.
MR. ORENT: I have multiple objections to the use of these documents by Dr. Iakovlev.
Particularly, one, to the extent that this contains information that may relate to the private healthcare information of individuals who Dr. Iakovlev has not intended to offer any specific testimonies on.
So to the extent that this relates to any protected healthcare information under HIPAA, I'm going to place an objection on the record to

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that.
Second, to the extent that it goes beyond the scope of any of his opinions, I would object to that.
And, I object to asking him to form new opinions on the basis of something that he's never seen before today.
And third, I'm not sure -- we have multiple questions. These are very new reports, and I'm not sure where the specimens originated from in all of these cases. So subject to those objections --
MS. BYARD: Has he signed a protective order?
MR. ORENT: He has not.
MS. BYARD: And so how would his review of these specimens be any different from the protected health information that you provide to him in the form of samples of human tissue?
MR. ORENT: He's retained as an expert and as a treating -- as a physician, he's subject to the code of medical ethics.
MS. BYARD: Okay.
BY MS. BYARD:
Q. Let me just ask you, Doctor, have

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you reviewed a pathological specimen for Ellen Hoffman?
MR. ORENT: And I'm also going to object, because that is -- to the extent that you're asking questions whether or not he's been a disclosed or undisclosed expert, he doesn't need to answer that question under Rule 26.
So I'm going to instruct you not to answer.
BY MS. BYARD:
Q. Are you going to follow Counsel's instruction?
A. Yes.
Q. Have you reviewed a specimen for Deborah Kilgore?
MR. ORENT: I need to consult with the witness on this.
MS. BYARD: Okay. We can go off the record.
THE VIDEOGRAPHER: Off the record at 9:50 a.m.
-- RECESS AT 9:50 --
-- UPON RESUMING AT 9:59 --
THE VIDEOGRAPHER: One moment, please. We're back on the record at 9:59 a.m.

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MR. ORENT: So, Counsel, and I have spoken off the record, and I've spoken with Dr. Iakovlev.
The issue that is concerning Plaintiffs' counsel for the MDL, is that there is the chance that we are moving from areas where Dr. Iakovlev has been disclosed as a testifying expert to areas where he may have been retained by individual case counsel in a consulting capacity.
First and foremost, Plaintiffs want to ensure that there's not going to be a waiver by allowing Dr. Iakovlev to testify to certain factual findings that he had. And consistent with that, we will allow him to testify to the factual nature of things that he saw, or didn't see.
However, we would -- we will object to any questions relating to his interactions with counsel, his interactions with counsel in terms of writing a report, or not writing a report, and the decision to file or not file a report in a particular case.
MS. BYARD: So what I'd like to do is, I'll ask my questions along the lines that you've just outlined. I will ask some questions to make a record in case I need it later.

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MR. ORENT: And I also --
MS. BYARD: And you can instruct him as you think prudent.
MR. ORENT: Okay. Just to be clear. By allowing us, allowing Dr. Iakovlev to answer questions as to his recollection about these particular samples, we're not waiving anything in terms of privileges, regarding communications or anything else in those cases, or generally speaking.
BY MS. BYARD:
Q. Let's return to my question then, Doctor, on Ellen Hoffman.
Did you review her pathology specimens?
A. I would have to check. (Witness reviews documents.)
Okay. She is not on this list. There is "Hoffman, Lori," but she is not on the list.
Q. Okay. So --
A. But --
Q. You know you didn't issue a report on Ellen Hoffman?
MR. ORENT: Objection.
THE WITNESS: I don't recall. But again, I don't remember now.

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BY MS. BYARD:
Q. And you can't tell me whether or not you reviewed her pathology or not --
A. If I --
Q. -- sitting here today?
A. If I didn't issue a report, I didn't review it.
Q. Okay.
A. Again, I mean, she's not on the list, so I don't recall now.
Q. Okay. Do you know whether or not there were cases where you formulated reports which were never disclosed to me?
MR. ORENT: Objection.
On that one, I'm going to instruct the witness not to answer.
THE WITNESS: You're instructing not to answer?
MR. ORENT: Yes.
THE WITNESS: Okay.
BY MS. BYARD:
Q. Are you aware of any instances when you've written reports on cases which were never ultimately provided?
MR. ORENT: Again, I'm going to

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instruct the witness not to answer.
BY MS. BYARD:
Q. Do you know if there are instances when counsel had pathological specimens that were never provided to you?
A. How would I know that?
Q. And returning to Deborah Kilgore, did you review pathology for her?
MR. ORENT: Again, subject to my prior objections.
THE WITNESS: She's not on the list.
BY MS. BYARD:
Q. And the list that you're referring to, is a list of cases where you have reports that have been noticed for the deposition, right?
A. Yes. And there are a few more, which are not on the list. But I may not recall it. I mean, there is a huge number, like there is 30. How can I remember all these names?
Q. Okay. You're not looking at a chain of custody for specimens that have been received by your lab, from Steelgate, are you?
A. No, we're not looking at that. I could have received some -- sometimes specimens come dry, and I cannot examine it. Or there is a

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piece of suture or calcification, something like this. I mean...
Q. Okay.
A. Or in some cases, it's not mesh, it's like a uterus or...
I think even for uterus, I issued a report but...
Q. So in some of the pathological specimens that you've received, there isn't even any mesh, right?
A. In some specimen, yeah, I receive sometimes just a -- it's mucosa, or scar tissue with some changes adjacent to the mesh, sometimes just mucosa.
Q. In those instances, you don't issue a report, do you?
MR. ORENT: Objection.
THE WITNESS: It depends. If I see --
MR. ORENT: I'm going to instruct the witness not to answer this particular question.
BY MS. BYARD:
Q. You'll acknowledge, though, won't you, that women have excisions following pelvic surgery resulting in specimens that don't include mesh; correct?

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A. Ask the question again.
Q. You'll acknowledge, though, won't you, that women have excisions following pelvic surgery, resulting in specimens that don't even contain mesh?
A. Yes. There are some specimens which don't contain mesh.
Q. Those were surgeries performed because women were experiencing complications, right?
MR. ORENT: Objection.
THE WITNESS: Specimens I received don't have mesh. But I don't know if they had mesh while they were processed in the original institution.
So what happens, original institution shaves off subtissue, puts it in the block, and the mesh is discarded.
So if it was original excised, and I didn't receive it, or it wasn't excised, this, this sometimes is a difficult question.
BY MS. BYARD:
Q. And you don't even know if the original institution shaved off the tissue or whether there was even mesh to begin with; correct?

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A. In some cases it's described in the pathology report, that they describe mesh; but they didn't submit sections.
Q. And in other --
A. If I have a pathology report. Sometimes I don't have a pathology report.
Q. Now, they use 120 samples that you speak of in your report. Do those include specimens that you received where you never ultimately issued a report?
A. Which report? That's a question, surgical pathology report, report which is served?
Q. Either one.
A. No. I enter only those cases I examine in one way or another and -- actually, those 120 samples, they had mesh. So I could find features specific for the mesh. Either mesh or features specific for the mesh.
Q. So these 120 exclude cases where there were no findings related to mesh?
A. No.
MR. ORENT: Objection.
BY MS. BYARD:
Q. Right?
A. That's not correct.

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So the specimen contains a mesh, and it's from vaginal area, then I examine it. If it's specimen -- sometimes, as I said, I receive a uterus. So why would I include the uterus -- findings of a uterus in a spreadsheet which is research -- which is made for research purposes for mesh.

So I examined those, I issue report for uterus, but then they don't use it for this purpose, research purpose. So it's not listed there. Or sometimes I receive three, four specimens for the same patient. Some of them have sort of piecemeal excision at the same time, or excisions are spread during time.

Q. So for any specimen that you receive, provided there is mesh, you issue a pathology report?

A. Sooner or later, I -- any specimen which came in and had to be registered at St. Michael's Hospital, I issue surgical pathology report.

Q. And does that include the specimens that you receive through Plaintiff's counsel?

A. Yes. It doesn't matter if it

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contains a mesh or doesn't contain a mesh, surgical pathology report needs to be issued. I have to sign it out as a diagnostic pathologist, and have to produce surgical pathology report.

Q. So irrespective of whether counsel ultimately disclosed a report for you in a case, you would have logged it when that specimen came in to you at St. Michael's; true?

MR. ORENT: Objection.

THE WITNESS: That's true. I cannot do staining or I cannot do anything without logging it in.

BY MS. BYARD:

Q. Okay. And so the 120 number would be your number of what -- the number of specimens that you had received?

A. 120 --

MR. ORENT: Objection.

THE WITNESS: 120 is mesh specimens. Those specimens I extracted knowledge about mesh body interactions. 120 is not a log number.

BY MS. BYARD:

Q. Do you have a log number?

A. It's in St. Michael's information system. And cases are accessioned and they are there.

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Assuming if I receive three, four specimens for the same patient, I get three, four different surgical pathology cases. Or, if two specimens were excised on the same day, they can be accessioned as one surgical number with A and B. It depends on the patient. Sometimes it's 1 and 2, A and B.

So, are you counting number of cases, or are you counting number of patients, or are you counting number of meshes? Some patients have three meshes.

Q. How do you log it?

A. We log by surgical number in St. Michael's Hospital. So if a specimen comes as a one, on one single requisition, marked A and B, it becomes one surgical number. Specimen A and specimen B. But sometimes I receive them spread in time, and then the accessioning becomes spread in time, so there are two surgical numbers.

Or, if I can catch it, when I receive it, then I can put it on the same number, just add it. Again, it's not straightforward sometimes.

Q. Okay. We don't have in your report the number of specimens that you've received by surgical number, do we?

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MR. ORENT: Objection.

THE WITNESS: No. I haven't logged them, those.

BY MS. BYARD:

Q. St. Michael's did, though, didn't they?

A. I mean, well, they don't count number of specimens received. I can try to do search by words, like "vaginal mesh" or something like this. But sometimes they come without definition of mesh, so accessioning clerk doesn't know that it's mesh, and it's just entered as "tissue." So this would escape search by word.

Q. So today, there's no way for us to recreate however many specimens you've received through the mesh litigation?

A. Exact up to single specimen? No, this would be difficult.

There is no -- I mean, in ballpark, yes. But, I mean, specifically trace each single specimen would be hard. Probably chain of custody forms, this would be easier. But then they are spread all over, I mean, from different sources.

Q. Do you have copies of all the chain of custody forms that you've received, the

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specimens you've received through the mesh litigation?

A. Yes, I do keep copies. But sometimes chain of custody forms comes in, and then there are three specimens behind it. They put on one chain of custody forms, and then next patient has three different specimens, which are coming from three different sources with three different chains of custody.

And sometimes chain of custody doesn't specify how many specimens, which shape they came in. I describe them in surgical pathology report each time I describe the specimen.

Q. Okay. So returning to specimens where you either haven't reviewed or haven't issued a report that we know of, this Connie Bennett case that I mentioned before; is that one that's familiar to you?

MR. ORENT: Subject to my same objections.

THE WITNESS: As I said, it's not a memory test. I cannot remember.

I don't remember the name. I may or may not have -- is it on the list?

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BY MS. BYARD:

Q. And again, you're looking at the list of your reports?

A. Yes. What was the last name?

Q. Connie Bennett, B-E-N-N-E-T-T?

A. (Witness reviews document.)

It's not on this list. I could have issued the report, could have. I don't remember now.

Q. Okay. I'll represent to you, Doctor, that these three cases are cases where my expert has received a specimen and issued a report, okay?

All I want to know from you, my question is whether you can tell me if you either didn't receive specimens for these women; or, a report that you did on your findings was never provided to me?

MR. ORENT: I'm going to instruct the witness not to answer those questions.

THE WITNESS: As per my counsel --

MS. BYARD: Are you going to follow your counsel?

THE WITNESS: I'm going to follow.

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BY MS. BYARD:

Q. In short, you can't assure to me that all of the specimens that are available through counsel, had been provided to you, can you?

A. How can I? I mean, I ask for everything available. Every time there is a new specimens, or a new set of specimens coming out, I'm asking for all available medical records and all available specimens.

Q. Beyond that, you can't assure, though, that your request has been fulfilled?

MR. ORENT: Objection.

BY MS. BYARD:

Q. Can you?

A. No.

Q. Similarly, you can't assure me that every specimen that you've examined has resulted in a report that's been provided to me, can you?

MR. ORENT: I'm instructing you not to answer.

BY MS. BYARD:

Q. Okay. Let's continue with this paragraph that we're looking at, if you don't mind, Doctor. It says:

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"My data pool of mesh explant samples contains specimens of St. Michael's Hospital patients, cases sent from outside hospitals, as well as potential and active litigation cases sent to me as consultant."

My only question here is on percentages. And I think you said you thought close to 70 of the 120 listed here were cases that came to you through litigation.

Do you have updated estimates for me of the number of samples that came from St. Michael's Hospital patients and the number sent from other hospitals?

MR. ORENT: Objection. I just want to clarify. He said 70 percent, not 70.

BY MS. BYARD:

Q. Oh, did you say 70?

A. Yes, 70 percent.

Q. Oh, thank you.

A. Roughly 70 percent, I think. It's an estimate.

Q. Okay. And then what are the percentages for the others?

A. I mean, 70 from litigation and 30, about 30 non-litigation.
Q. So 30 either from St. Michael's or from outside hospitals?
A. It's mainly St. Michael's. For transvaginal, it's mainly St. Michael's Hospital.
Q. For the outside hospitals, do you know how they select which samples they give to you and which they don't?
A. Those clinicians, they just send whatever is available, consecutive.
(Reporter sought clarification.)
A. Consecutive.
Q. But if there are samples that they don't send to you, you wouldn't know about that one way or the other, would you?
A. No.
MR. ORENT: Objection.
BY MS. BYARD:
Q. Okay. Turning to the next page, the first full paragraph.
And I'm on page 3 of 1196 for the record?
A. Yes.
Q. You talk about how pathologists

are trained and develop skills for subjective assessments?
A. That's correct.
Q. You write that:
"To understand the related pathological processes and make a correct diagnosis, pathologists need to understand the function of the devices being analyzed --"
A. That's correct.
Q. "-- their physical characteristics --"
A. That's correct.
Q. "-- surgical and other techniques introducing the objects into the body."
Right?
A. That's correct.
Q. Speaking of the devices, is the Solyx a sling or a pelvic organ prolapse device?
MR. ORENT: Objection.
THE WITNESS: As far as I remember, Solyx is a sling.
BY MS. BYARD:
Q. Is Polyform indicated for slings or for treatment of pelvic organ prolapse?
A. Polyform is just a name of a type

of mesh, or more of a raw mesh.
(Reporter sought clarification.)
A. Raw material, raw material of the mesh. It's not formal device.
Q. Is the Prefyx a sling, or is it indicated for the treatment of pelvic organ prolapse?
A. Prefyx, I'm not sure about this one.
Q. How about the Advantage Fit?
A. Advantage is -- I would have to check. I mean, it's not a memory test. Every time I see some name I'm not sure, I just Google and check with Boston Scientific website.
Q. Sitting here today, though, you can't tell me?
MR. ORENT: Objection.
THE WITNESS: I wouldn't guess. I don't want to guess.
BY MS. BYARD:
Q. What about Uphold? Is that indicated for stress urinary incontinence or for pelvic organ prolapse?
A. Pelvic organ prolapse.
Q. How many incisions are used to

place a Solyx?
A. It's a clinical question. I'm not a clinician.
Q. Where is the incision or incisions located?
MR. ORENT: Objection.
THE WITNESS: For which type?
BY MS. BYARD:
Q. Solyx.
A. So my understanding is for slings, there is a midline incision, and then there are devices usually trocars used to push the devices further. But the incision is midline to open the area.
Q. Does the Obtryx make use of one incision or more than one incision?
MR. ORENT: Objection.
THE WITNESS: You mean the linear incision or trocar tracks?
BY MS. BYARD:
Q. Either way.
A. Linear incision is one, as far as I understand, in the middle. And then there are trocar tracks.
Q. I'm sorry?

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A. Which go through skin, so there -- you need to make an incision in the skin. But then it's not an incision linear.
Q. Where does the -- what you're calling the trocar track, or the trocar pass, compare in location for an Obtryx versus retropubic sling, for instance?
MR. ORENT: Objection.
THE WITNESS: A retropubic sling doesn't go into a transobturator. So the arms go retropubically, pointing upward. So it's --
BY MS. BYARD:
Q. Where do the incisions for the trocar tracks -- let me start over.
How do the incisions for the trocar tracks or passes for the Obtryx sling compare to the Advantage sling?
MR. ORENT: Objection.
THE WITNESS: I think we are going beyond the scope of what pathologists need to understand.
I need to understand if the sling is placed in specific anatomical area, and what anatomical spaces are displaced. Specific details of surgical techniques need to be understood only

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to a degree, which helps me to understand the function.
So you're asking me very specific details which would be important for a clinician, but as a pathologist, they are not as important to me. So, I think we're going beyond what I would need to know.
BY MS. BYARD:
Q. Well, would the Obtryx device or the Uphold device pass closer to the pudendal nerve?
MR. ORENT: Objection.
THE WITNESS: Obtryx or Uphold. I cannot tell you which one would be closer. Again, this would be irrelevant, because I see nerve ingrowth in both, and it doesn't matter if it's coming from a pudendal nerve or any other nerve or smaller branch.
BY MS. BYARD:
Q. Does it matter for a patient's clinical symptomology whether or not there's involvement of the pudendal nerve versus other nerves?
A. What matters is involvement of a nerve. If it has a name, it doesn't matter.

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Q. So it's your testimony that the treatment modalities wouldn't differ depending on whether a pudendal nerve branch versus another nerve branch were ingrown in mesh?
A. No.
MR. ORENT: Objection.
BY MS. BYARD:
Q. The reality is that you don't treat clinical complications from pelvic mesh, do you?
MR. ORENT: Objection.
THE WITNESS: No.
BY MS. BYARD:
Q. And so you don't need to understand, as a pathologist, from your perspective, whether or not the nerve that you see is a pudendal nerve, or part of an obturator nerve, or part of the genital femoral nerves, right?
A. I think you're misrepresenting. You're talking about large nerves, large branches so -- which have names. There will be thousands of other smaller branches, which don't have names.
So you're making it kind of like a cartoon, more of a -- reality is different. The genital area is very richly innervated, nerves

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coming from different places. You're talking about large nerve, but the branches have no names, and then they go in the area. So it's either you have a misunderstanding, or just trying to make it look like this.
MS. BYARD: Object and move to strike.
MR. ORENT: Oppose.
BY MS. BYARD:
Q. Does the Uphold fix to any specific anatomical structures in the female pelvis?
MR. ORENT: Objection.
THE WITNESS: What do you mean "fixed"? By stitches?
BY MS. BYARD:
Q. Sure.
A. No, there are no stitches.
Q. Is it affixed to any other anatomical landmarks in the pelvis?
MR. ORENT: Objection. Scope.
THE WITNESS: I have to ask questions, how it is fixed? I mean, is it fixed by stitching, or it's fixed by ingrowth?
BY MS. BYARD:
Q. Either one.

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A. Specifically, the meshes are not stitched to tissues. So they mainly depend on tissue ingrowth.
Q. How about fixed by placement to any of the anatomical structures of the pelvis? Do you know whether that occurs?
MR. ORENT: Objection.
THE WITNESS: What do you mean, "fixed by placement"?
Placement is just you place something.
BY MS. BYARD:
Q. What is the Capio?
A. Pardon?
Q. The Capio?
A. I don't know what you're talking about.
MR. ORENT: Objection. Scope.
BY MS. BYARD:
Q. Do Boston Scientific's pelvic mesh products make use of trocars?
MR. ORENT: Objection. Vague. Form. Scope.
THE WITNESS: What do you mean?
BY MS. BYARD:
Q. You used the word "trocars" before. What did you mean by that?

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A. It's a device which comes in the kit. It's more of like a long needle.
Q. Do Boston Scientific's pelvic organ prolapse kits make use of trocars?
MR. ORENT: Objection.
THE WITNESS: Yes, they're included in the kits.
BY MS. BYARD:
Q. Doctor, if I asked you to describe how you perform a Kelly plication, would you be able to do that?
MR. ORENT: Objection. Outside the scope.
THE WITNESS: I'm a pathologist. I don't do --
BY MS. BYARD:
Q. Okay. Same thing for perineorrhaphy?
MR. ORENT: Objection. And similarly, I think these questions are designed to embarrass or offend the witness.
MS. BYARD: No. I'm asking the questions I need to ask, John. So I object to the colloquy.
MR. ORENT: They're ridiculous questions for a pathologist.

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THE WITNESS: I mean, you're asking me questions which clearly are clinical questions.
BY MS. BYARD:
Q. Okay.
A. As I said, as a pathologist I need to understand what the device looks like, what is it made from, and what anatomical location it is placed, what is its function.
That's as much -- that's, basically, generally what I need to know. You're going to somewhere where it's completely beyond my scope, my expertise.
Q. You write in your report that you need to understand the function of the devices being analyzed, right?
A. Yes.
Q. You write that you need to know the devices' physical characteristics, right?
MR. ORENT: Objection. These are --
THE WITNESS: The functions for stress urinary incontinence is to support urethra.
Physical characteristics, I see it's a polypropylene, it's not biological mesh. That's what I'm talking about.

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BY MS. BYARD:
Q. Okay. But as far as where these devices pass in the anatomy, based on their surgical placement, you haven't been able to tell me that with specificity, because those are better questions for a clinician; correct?
A. No --
MR. ORENT: Objection.
THE WITNESS: -- this is not correct. I know where they are placed. You are asking me how they are placed, and this is the difference.
Because I don't need to know exact very specific details how they are placed. But, in general, where they are placed and what anatomical sort of locations are they placed -- that's generally what I need to understand.
If I need very specific questions, if there is a very specific question for specific diagnostic procedure, then I would go and consult with clinician. Like a placement of a stent, which artery it was placed in the heart, was it LED or it was circumflex? I mean, these would be very specific. So what kind of stent it was, so if I cannot find it.
But you're asking me trocar incisions

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and other things. I mean, I receive specimen six years later when all incisions are healed.

BY MS. BYARD:

Q. Does the location of the incision help you understand where the device was anatomically located when it was actually in the patient's body?

A. It can be very long way from incision to the placement of the device. So it may or may not help, but most of the time --

For example, if it's a hernia, if it's open hernia, I know that there was incision from skin. So it's open hernia surgery.

If it's laparoscopic, I know that the access was laparoscopically. So it's a different anatomical location. So a laparoscopic hernia would be more of an intraperitoneal access. That makes a difference.

If you put sling through incision one centimeter to the left or right, it will not make a difference.

Q. So whether --

A. But it might make a difference for a surgeon.

Q. So whether or not the sling is

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placed in the retropubic space as opposed to through the transobturator space doesn't make a difference to you as a pathologist?

A. It does make a difference.

As I said, this is an anatomical location, that's what I'm -- I try to understand every time I encounter a new device. But how it was placed specifically, all intricate details of surgical techniques, they're irrelevant for this.

Q. Moving to the third paragraph, the third full paragraph on page 3, please, Doctor.

A. Yes.

Q. You write that you have been able to:

"Directly observe changes in the mesh samples, including but not limited to scar encapsulation, scar maturation with contraction, the inflammatory response to the implanted mesh, including but not limited to the foreign body reaction and chronic lymphoplasmacytic inflammation --"

A. Plasmacytic.

Q. Thank you.

"-- vascular congestion and

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edema within mesh compartments, as well as innervation with nerve ingrowth into the mesh compartments, vascular abnormalities and mesh degradation."

Did I read that all reasonably correctly?

A. That's correct.

Q. How do you define chronic lymphoplasmacytic --

A. Cytic.

Q. -- cytic inflammation composed of foreign body reaction?

A. Foreign body reaction, as I explained before, is a collection of epithelioid histiocytes, these are mononucleated or multinucleated. Lymphoplasmacytic, as the word implies, is lymphocytes and plasma cells.

Q. How do you define vascular congestion?

A. If the vessels are enlarged, then fully packed with red blood cells.

Q. What did you mean by "vascular abnormalities"?

A. I see obliterated arteries. I see

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thrombosed capillaries.

Q. And for a lay person, what does obliterated arteries and thrombose capillaries mean?

A. A vessel which doesn't supply blood anymore.

Q. Are you able to tell, microscopically, when that obliteration occurred?

A. To a certain degree.

Q. How so?

A. Sometimes I can say that it's been week or even month, maybe years, or sometimes it's a relatively recent event, days. Or hours.

Q. But how do you discern that microscopically, I think was my question?

A. Oh, then I would have to give you a lecture. Vital response, the stages of tissue reacting to a blocked vessel.

First, inflammatory cells, then there would be changes in the vascular wall, organization of the thrombus, recolonization.

Q. And so when you say you observe an obliterated artery, for instance, would you typically, as a pathologist, record whether or not you saw these tissue reactions to the inciting

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event?
A. Depends on clinical relevance. For example, if there is autopsy case and I see that the arteries in the heart is obliterated, it will depend. If it's an old injury, definitely it wasn't cause of death. If it's fresh injury, this can be cause of death. This is just an example.
Q. And what is thrombosed capillary? What does that term mean for a lay person?
A. Capillaries doesn't supply blood anymore.
Q. Turning to your list of articles that you've set forth here, this list, did you intend it to include all of your publications, abstracts, lectures, oral and poster presentations pertinent to the subject of your report?
A. Pertinent to my mesh research, yes.
Q. Okay. All of these are from 2014, right?
A. Yes.
Q. I'd like to --
A. Just one was earlier. When we started --
Q. Oh, yes. "The Pathological

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Findings in Explanted Surgical Meshes," that presentation --
A. Yes.
Q. -- that you gave?
A. The work, as I said, started in 2012.
Q. For hernia mesh, right?
A. Yeah. I think I received first transvaginal mesh very soon, January or February of -- or looked at it, I mean. It could have been St. Michael's Hospital transvaginal mesh, which is -- I don't remember now.
Q. Yeah, but 2013?
A. All in 2013, yes.
Q. Okay. All of these publications, though, with the exception of this oral presentation, are from 2014, right?
A. Yes. Most of the work was done -- completed in 2014.
Q. And I understand the publication process takes some time, okay. That's not what I'm -- I don't intend to quibble with you about that at all.
I want to walk through these before we get into any detail in them. The first is an article that you published with Dr. Erin Teeter

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Carey and Dr. John Steege, "Pathology of Explanted Transvaginal Meshes," International Journal of Medical Health, Pharmaceutical and Biomedical Engineering, 2014; is that right?
A. Correct.
Q. The second is an article published with Dr. Bendavid, Dr. Lou and Koch, "Mesh-Related SIN Syndrome: A Surreptitious, Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain," International Journal of Clinical Medicine, 2014.
These are both full published articles, right?
A. Yes, these are full articles.
Q. And then we have a list of abstracts. And there's five listed here, right?
A. No, there are more. They're all included on the flash drive.
Q. There are five listed here, right?
A. On this page, yes, there are five.
Q. How many more are there on that thumb drive?
A. Maybe a couple. I don't remember now.
Q. And you put this list together sometime around November 10th, 2014, right?

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A. October, November, yeah.
Q. So the abstracts that are -- you have on your thumb drive, the abstracts that are in addition to this list that are available on this thumb drive, were published since November 10th of 2014?
A. Either published or presented. So I usually put something published or presented on my CV. Not something which was been accepted.
Q. Okay.
A. But sometimes depends. Sometimes I put something that has been accepted, but hasn't been presented.
Q. Let's look at these five abstracts. The first one is published by you and Dr. Mekel and Blaivas?
A. That's correct.
Q. "Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh Is Not Inert," the International Continence Society Annual Meeting, 2014, right?
A. That's correct.
Q. And then the next one, Dunn, Guelcher and you: "Failure Analysis of Transvaginal

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Mesh Products: A Biomaterials Perspective Using Materials Science Fundamentals," 2014.
A. That's correct.
Q. Number three is Vladimir Iakovlev: "Explanted Surgical Meshes: What Pathologists and Industry Failed to Do for 50 Years," 2014, right?
A. That's correct.
Q. Yourself, Dr. Guelcher and Dr. Bendavid: "In-vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades," 2014. Right?
A. That's correct.
Q. Number five is an abstract with yourself, Dr. Erin Teeter Carey, Dr. Iakovleva --
A. Yes.
Q. -- Dr. Steege and Dr. Bendavid: "Pathological Findings Associated with Pain in Transvaginal Meshes."
A. That's correct.
Q. 2014.
And then you list here some lectures and oral presentations.
This first one, is a copy of that included in materials that you've provided on the thumb drive?

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A. Yes. I included all what I could at this stage, I mean, whatever I had.
Q. Okay. And number two, is that essentially a duplication of the fully published article number one on your list?
A. Well, it's a duplication of the title. So what happens with some conferences or other meetings, it's a bit an abstract. Abstract is accepted, it's published either in special journal issue, and then they make a decision, if you make an oral presentation, or you make a poster presentation.
So then abstract is duplicated as oral presentation or poster presentation, because abstract you describe your work to the peer review process, and then there is a decision how you present it.
So it becomes presented twice. One in the form of abstract, and then one in the form of presentation. Either oral presentation or poster presentation.
Q. Okay. So for all these articles and abstracts, the two articles, the five abstracts, this list then of lectures and oral presentations or poster presentations, are

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presentations forms of the articles and abstracts?
A. Not all of them. For the Canadian hernia meetings, I was just invited to come without abstracts.
Q. Okay. Can you point those out to me?
A. This, number one.
Q. Okay.
A. (Witness reviews document.)
This was just an invitation. Number three, also just an invitation. Number five --
Q. Okay.
A. -- this was just an invitation.
Yup.
MR. ORENT: When we get to a good breaking point, we can take our first break.
MS. BYARD: Now is a fine time for me.
MR. ORENT: Okay.
THE VIDEOGRAPHER: This marks the end of media number one, in the deposition of Dr. Vladimir Iakovlev.
We're going off the record at 10:43 a.m.
-- RECESS AT 10:43 --
EXHIBIT NO. 1197: Article entitled, "Mesh-Related SIN Syndrome: A Surreptitious Irreversible Neuralgia

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and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain," International Journal of Clinical Medicine, 2014, by Dr. R. Bendavid, Dr. W. Lou, Dr. A. Koch and Dr. V. Iakovlev.
-- UPON RESUMING AT 11:03 --
THE VIDEOGRAPHER: Here begins media number two in the deposition of Dr. Vladimir Iakovlev.
We're back on the record at 11:03 a.m.
BY MS. BYARD:
Q. Doctor, I'll hand you what's been marked as 1197. Counsel.
MR. ORENT: Thank you.
BY MS. BYARD:
Q. Doctor, do you recognize Exhibit 1197?
A. Yes.
Q. What is it?
A. It's published article, co-authored by me.
Q. So these other doctors listed on the article are Dr. Bendavid, Dr. Lou and Dr. Koch; do you see that?
A. Yes.

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Q. Do these doctors use mesh and hernia repair, to your knowledge?
A. Yes. Except for Dr. Lou, she's a statistician.
Q. Presently Dr. Bendavid continues to use polypropylene mesh for the treatment of abdominal hernia repair; correct?
MR. ORENT: Objection.
THE WITNESS: No. Actually, he uses native tissue to repair. He takes out meshes.
BY MS. BYARD:
Q. Did there come a time when his practice changed in that regard, to your knowledge?
A. It depends. I mean, in some patients you just have no choice. You have to use, like, um, central large defects.
Q. So he makes a patient -- your understanding is that Dr. Bendavid makes a patient-specific determination about whether or not to use polypropylene mesh in hernia repair?
MR. ORENT: Objection.
THE WITNESS: That's correct.
BY MS. BYARD:
Q. Is the same true for Dr. Andreas Koch?

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A. Koch.
MR. ORENT: Objection.
BY MS. BYARD:
Q. Koch?
A. Yes.
Q. Okay. Explain to the jury what a controlled study is.
A. Where is the jury?
Q. (Indicates.)
A. Okay. You mean controlled clinical study?
Q. Just in general, what a controlled study is. Whether it's in a clinical setting, or in your laboratory?
A. "Controlled" usually implies to a clinical study, so if it's in a laboratory it wouldn't be controlled.
Controlled is a prospective study where patients are registered and specific statistical requirements for this.
Q. In this study with Dr. Bendavid, you used ten specimens, in three groups; in each of three groups. You looked at virgin tissue, you looked at scar tissue, and you looked at explanted mesh from the posterior inguinal wall; correct?

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A. That's correct.
Q. Would you describe this study as having been controlled through the use of virgin tissue and scar tissue?
A. No. As I said, control is a specific statistical term for clinical prospective studies.
Q. How would you describe this study then?
A. This was a prospective study.
Q. Why was it important for the study to use virgin tissue, scar tissue, and explanted mesh specimens in comparison to one another?
A. There were two questions. First question was, if nerve ingrowth occurs in the mesh which has been reported even before this paper.
And the second question was, what's the nerve density in comparison with virgin tissue and scar without mesh. If mesh inhibits nerve ingrowth; and if it inhibits, to what degree. Sort of establishes a baseline for these parameters.
Q. So you used virgin tissue and scar tissue in order to establish a baseline for the comparison to mesh that you were making in terms of nerve proliferation in tissue, correct?

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A. Mesh and scar were more of a controls in this study. I mean virgin, was more of a control. But baseline was between all of those three types of tissue.
Q. So explain to the jury what you mean by "control".
MR. ORENT: Objection.
THE WITNESS: I didn't mean control. Where did I say "control"? Control, you mean control samples?
BY MS. BYARD:
Q. Yes.
A. Sorry, I misunderstood you.
Control sample is a sample which is used for comparison, something which implies doesn't have any changes.
Something neutral, normal, or something which has been exposed to only methodology manipulations, rather than biological processes which are being studied.
BY MS. BYARD:
Q. And similarly, you've used scar tissue in this study as a control to understand if there were differences related to the mesh?
A. Yes. So mesh is encapsulated by

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scar tissue. So control for scar around and inside the mesh would be scar without mesh. So the same area, surgical procedure, all of those are variables are the same, except one group has mesh and the other group doesn't have mesh.

Q. Other terms that are used to describe study designs include "randomized studies" or "blinded studies"; are you familiar with those terms?

A. Yes, I am.

Q. Is it fair to say that this was a controlled study, but not randomized or blinded?

A. You're just using it in different -- randomized, controlled studies -- these are all clinical terms, specific statistical methods for clinical prospective studies when a drug is tested or a new device is tested. So the patients are randomized before they are given treatment. And then they follow this cohorts. And then there is statistical methods to follow that, and there are specific requirements for that.

In this case, it's not applicable, because there were no new device, no new medication introduced. And the randomization is done before the device is being inserted, or new medication is

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given. You cannot randomize it after. So it's completely different, we are talking about completely different scenarios.

Q. Well, and it wasn't blinded in the sense that you knew whether the specimen that you were looking at was native tissue or virgin tissue, whether it was scar tissue or whether it was mesh, correct?

A. Blinded, again, it's more of a clinical terminology when you do controlled studies.

So either patients are blinded, or researchers are blinded. I mean, there was a degree of blindness in this study. But again, talking about completely different statistical scenarios, completely different approaches.

Q. What do you mean by, there was a degree of blinded in this study?

A. When I was examining them, I was examining them without knowledge of other clinical variables. I could clearly see that there's no mesh in it; if it's scar or not scar.

But then I didn't know if there were comorbidities, other possible clinical variables.

Q. So here you examined the samples

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for nerve density, nerve size, and nerve and vessel ingrowth, correct?

A. That's correct. Well, we assessed the specimen, so we observed what was abnormal in the microscope. So the main hypothesis and main focus was nerve ingrowth, but then there were other microscopic findings within mesh specimens which were observed.

Q. You found that there were no significant differences in nerve density between virgin scar and mesh samples, correct?

A. Yeah, that's correct. In that sample size, there was no statistical significant difference.

Q. You concluded that the presence of mesh does not significantly affect nerve density, right?

A. It's the same statement as before.

Q. You concluded that -- you concluded, though, that the nerves and their terminal ends were in a volnerable position about the mesh and within its pores?

A. That was additional findings, because we observed changes of the scar tissue within the mesh, because it was different from the

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scar without the mesh.

Q. How so?

A. It's all described in the paper. There are vascular congestion, edema, inflammation, foreign body type, chronic lymphoplasmacytic inflammation.

(Reporter sought clarification.)

A. Foreign body type inflammation, and chronic lymphoplasmacytic inflammation.

MR. ORENT: L-Y-M-P-H-O-P-L-A-S-M-A-C-Y-T-I-C.

BY MS. BYARD:

Q. What did you mean by "in a vulnerable position"?

A. In a pathologically changed tissue, mainly it is compartmentalization of the mesh. So what happens, the scar tissue within the mesh is divided into compartments. So, essentially, there are little gates or bottlenecks in the mesh. And this mainly causes the problem.

Because it's compartment, it's enclosed compartment. Like tooth pulp, this is best analogy. It gets inflamed; you feel pain.

Q. You didn't write here, though, that the compartmentalization of nerves in mesh is what caused clinical complications in these

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patients. You wrote that they were in a vulnerable position, correct?
A. In the text, I think there is compartmentalization discussion.
Q. Well, what you wrote, though, was that nerve receptors were exposed to potential mechanical and chemical factors: Scarring, entrapment, compression, tugging, deformation, contraction, hypoxia/acidosis, inflammation and edema. That's what you wrote; correct?
A. That's an abstract.
MR. ORENT: Objection.
THE WITNESS: You're reading an abstract. I'm saying that there is discussion longer in the text.
BY MS. BYARD:
Q. Is that what appears in the abstract, sir?
A. You just read it, yes.
Q. In the introduction, the last sentence reads:
"The mesh in question is polypropylene, the most widely used polymer in hernia repair." Correct?
A. That's correct.

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Q. There's a discussion here under your methods, that the mesh samples --
"The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two blocks, additional blocks were taken until penetration was directed."
Do you see that?
A. "Detected".
Q. Thank you. Do you see that?
A. Yes.
Q. Did you perform the same type of sampling for microscopic evaluation in your examinations of transvaginal mesh?
A. No, there was no need. The nerve density is so much higher in transvaginal meshes, that pretty much very small piece would contain it.
Q. So unlike this study on hernia mesh, for transvaginal mesh you didn't initially sample the specimens to determine if you could detect nerve ingrowth or not?
MR. ORENT: Objection.
THE WITNESS: For transvaginal meshes I don't submit additional sections. I just submit

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what I think is -- well, usually, it is what is available.
If it's a large POP device, I submit representative sections. Usually not more than three blocks. I never needed to submit more tissue. Either I submitted everything, or it was satisfactory for examination to submit what I submitted first time.
BY MS. BYARD:
Q. What do you mean by "representative sections"?
A. Representative of the sample.
Q. And how do you determine that?
A. According to my training and experience.
Q. Are you taking, though, when you examine transvaginal mesh specimens, are you taking samples or sections that you determine are representative based on your training?
A. Yes.
MR. ORENT: Objection.
BY MS. BYARD:
Q. In the second full paragraph under methods you write:
"If a peripheral nerve was seen

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an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore."
Right?
A. That's correct.
Q. Tell me what you mean by "imaginary line"?
A. Do you want me to draw or -- that would be easier.
Q. We might do that later. Can you try and explain it to me in words?
A. Essentially this describes the boundaries of a mesh area, area which is occupied by mesh, which by definition would be new tissue. Tissue which appeared after the mesh was placed.
Q. So when you look at a slide, you see either a clear space or a whole space where you determine that the mesh was or is and can't be seen, right?
MR. ORENT: Objection.
THE WITNESS: What I see in the microscope, I see cross-sections of the filaments, they are clear, yes, you are right.
So I can see the outermost points of

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the mesh filaments. Therefore, anything inside this boundaries, is new tissue which was generated after mesh was placed.

It was an artificial sort of distinction for us to understand during this study, which nerves were new, new innervation or reinnervation. And which nerves could have been trapped in the scar which was expanding into normal tissue.

BY MS. BYARD:

Q. To identify when looking -- let me start over.

When looking at transvaginal mesh slides under microscope, you have to draw the same imaginary line connecting the outermost points of the adjacent mesh filaments in order to record whether nerves are ingrown in the mesh, are whether they were preexisting, correct?

A. Yes, I mean this would be a very strict criteria. Because some nerve branches just outside of the imaginary line can still be new ones. But, I mean, anything beyond those lines is new, by definition.

But the one I assess, I make a distinction. Especially if I collect data for

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research product. But for symptoms as a diagnostic tool, it doesn't have much significance.

Because as I said, I mean, nerves right -- just outside that line, can be affected to the same degree as -- it might be microns difference, here or there, so -- but that was important for this study, to understand it as diagnostically this doesn't have much significance.

Q. Do you know, or did your -- I'm sorry, let me start over.

Did your research here, look at how, diagnostically, nerves growing outside of mesh or preexisting nerves, compared in terms of clinical complications to nerves growing within the mesh?

A. In this study?

Q. (Nods.)

A. In this study, we, as I said, establish baseline.

Q. So the answer to my question is, "no, you did not," right?

MR. ORENT: Objection.

THE WITNESS: Well, you see that there is no specific correlation with clinical presentation in this specific study.

BY MS. BYARD:

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Q. And this same process that you describe here in this study of drawing an imaginary line connecting the outermost points of the adjacent mesh filaments, is the same process by which you determined the shape of the mesh when looking at transvaginal specimens, correct?

A. No, I don't understand your question. Shape in nerves -- they are different issues.

Q. Okay. Let me take it then the way that you've presented it.

This same process that you describe in the study of drawing an imaginary line connecting the outermost points of adjacent mesh filaments, in order to determine whether nerves were there beforehand, or whether they grew into the mesh, is the same method that you applied to your analysis of transvaginal mesh specimens in the litigation, correct?

A. In litigation, I describe nerve involvement. I mean, they might be ingrown; they might be just outside.

As I said, diagnostically, if the nerve is affected, it could be outside of the imaginary line. It can be trapped in the scar tissue or

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around.

I think it is a little artificial to hook on this imaginary line. It was done for the research project. As I said, diagnostically, what matters is, if there is an innervation in the tissue, in that tissue. That's important.

Q. To determine whether or not a nerve had ingrown into mesh, though, when you were looking at transvaginal mesh specimens, you had to draw this imaginary line connecting the outermost points of adjacent mesh filaments?

A. If I want to call it ingrown, yes, it's important. But diagnostically, is it -- if only ingrown nerves are important for diagnostic purposes, this is not correct.

Because ingrown nerves which are inside the compartment, they are much deeper. But at the same time, if a nerve is just outside, it branches, and then supplies nerve endings, small branches in the tissue inside.

Q. Please listen to my question, sir.

In order to determine whether nerve was ingrown in mesh, when examining transvaginal mesh specimens, you had to draw this same imaginary line that you describe in your study with Bendavid,

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connecting the outermost points of adjacent mesh filaments, didn't you?
MR. ORENT: Objection. Asked and answered. Moreover, Dr. Iakovlev is entitled to give a full and complete response to the questions and he will continue to do so and --
MS. BYARD: Please limit your objections to form, sir.
MR. ORENT: Asked and answered.
THE WITNESS: As I said, in the description if I say ingrown, I use this imaginary line. But diagnostically, this has not -- it doesn't have much significance. Because what I do in diagnostically, I try to estimate or assess if the tissue is innervated. That's what important.
BY MS. BYARD:
Q. But whether you determine that a nerve was ingrown, depends completely on whether it lies within the parameters of this imaginary line that you've drawn?
MR. ORENT: Objection. Asked and answered.
THE WITNESS: Ingrown where? Ingrown in the scar, or ingrown inside the mesh?
BY MS. BYARD:

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Q. Ingrown inside the mesh, please.
A. If it's ingrown inside the mesh and I make a statement --
MR. ORENT: Objection.
THE WITNESS: -- that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue.
I think we are mixing up diagnostic process with our research.
Descriptive term can be, if I make a statement if it's ingrown in the mesh, I used that imaginary line.
BY MS. BYARD:
Q. Thank you.
Part of what you did in the study with Dr. Bendavid included calculating an adjustment ratio between specimens to come to a more accurate picture of the rate of nerve ingrowth, correct?
A. Not rate, density.
Q. Density, thank you.
With respect to your examination of transvaginal mesh for the litigation, you didn't evaluate nerve density at the technical level that you did for the study on hernia repair; correct?

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MR. ORENT: Objection.
THE WITNESS: No.
BY MS. BYARD:
Q. And so you didn't adjust -- calculate an adjustment ratio, and your examination and analysis of transvaginal mesh for litigation, correct?
MR. ORENT: Objection.
THE WITNESS: Again, we are going from research from scientific question to diagnostic processes.
I don't base my opinion on adjustment ratios or on the specifics of what I did in the research part. I don't --
BY MS. BYARD:
Q. My only question is whether you did it?
A. I never used it. It was only used once for this specific study, for specific question. It wasn't diagnostic question. It was more of a mathematical question.
Q. I want to turn to page 802 of 1197.
The last two full sentences before the figures read:
"The branches located at the

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mesh interface tended to have an orientation parallel to the mesh plane."
A. That's correct.
Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of nerves into the mesh structure. Table 1."
A. That is correct.
Q. What do you mean by, "the branches at the mesh interface tending to have an orientation parallel to the mesh plane"?
A. They had orientation parallel to the mesh plane.
Q. So the majority of the nerves that were located at the mesh interface were running parallel to the mesh as opposed to through it?
A. Yes, that's how you would orient any cable. Just think about cables. There's a cable, and then you run it in the corner because there is an obstacle here, and then there are branches which go into the ceiling, or the walls, or somewhere else; so you can imagine the same way.

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Nerve branch goes along the plane, and then there are small branches going into the mesh and they innervate inside tissue. It's logical biological.

Q. Is this same finding -- let me start over.

Were your findings about the orientation of the branches of nerves located at the mesh interface similar for transvaginal mesh as you've described here for hernia mesh?

A. Transvaginal mesh is different because there are no anatomical planes. In the hernia, in the anterior abdominal wall, you have layers which are separated by fascia, serrated muscle, so there are anatomical planes.

In transvaginal location, there is no anatomical plane. Tissues just merge into each other. The orientation of nerves is a little bit different, because in the anterior abdominal wall, most of the nerves run parallel to supply further; so the mesh is placed parallel.

In the transvaginal location, the nerve branches are running to innervate mucosa. And the mesh is placed perpendicular, so this is completely a different anatomical structure.

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So in transvaginal meshes, they are all over the place, and I did not see that predominance of parallel orientation. It's different anatomical structure.

Q. You write that the number of nerves ingrown -- and I've switched to page 803. On page 803, the first full sentence you write:

"The number of nerves ingrown into the mesh structures range from one to three per examined portion of a specimen."

Correct?

A. That's correct.

Q. Were your findings in examining transvaginal mesh specimens similar to your findings here on hernia mesh?

A. No. Densities are much higher in transvaginal meshes. About six times on average than in inguinal hernia.

Q. So when you see the number of nerves ingrown into mesh structures and hernia repair ranging from one to three per examined portion of the mesh; the number would be closer to 6 to 18 nerves per examined specimen for transvaginal mesh? Is that your testimony?

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A. No, this is not my testimony. It's higher. And on an average, the last time I calculated, it's about six times higher. What is an average number of nerves I see, and I'm talking about densities, which was about six times higher.

Number of nerves I see, I don't know now. It's much higher. I mean, it's definitely not one to three, it's about beyond ten or so.

And then it depends, I mean, what device we are talking about. Sling, slings tend to have smaller specimens. POP devices, it might be over a hundred of nerves that I see in one section, it depends.

Q. So the way you went about arriving at this number for your valuation of hernia repair, was to actually count the number of nerves per specimen, correct?

A. That's correct.

Q. And you haven't done that counting activity for transvaginal mesh specimens?

A. I have not.

MR. ORENT: Objection.

THE WITNESS: There are reports, completed surgical pathology reports with synoptic data, and there is a full count.

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Again, it's not what I am basing my opinion, but this was done more for research purpose later on.

BY MS. BYARD:

Q. Okay. So in answer to my question, you haven't done this type of overall analysis of counting the nerves, the number of nerves that you see grown into mesh structure for transvaginal mesh, right?

MR. ORENT: Objection. Asked and answered.

THE WITNESS: I have done it. When the complete surgical report is issued, it contains these numbers.

BY MS. BYARD:

Q. Whose complete surgical report?

A. There's some, I think I completed it to -- when I sign out a surgical pathology report in St. Michael's system, I include full analysis for nerve report -- nerve densities.

Q. So there are some cases where you've completed a complete St. Michael's surgical pathology report and others where you haven't, correct?

A. For most of this, I didn't have

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time to complete the surgical pathology reports.
But you have at least one here, I think for Ms. Holland.
MR. ORENT: Tab 1.
BY MS. BYARD:
Q. I know what you're referring to and we'll look at that tomorrow.
A. Okay.
Q. Take the time you need, I know what you're referring to, though.
A. So how this is done, when I --
Q. That's okay, there's no question pending.
MR. ORENT: That's the report you're looking for?
THE WITNESS: Yeah, the densities here, right there.
BY MS. BYARD:
Q. So my question is focused on your analysis -- which case is that?
A. This one.
MR. ORENT: Lucy Allen.
MS. BYARD: Okay.
(Reporter sought clarification).
MR. ORENT: Lucy Allen.

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And he's pointing to the line that reads, "was it 59 branches?"
BY MS. BYARD:
Q. Okay. So my question is focused on the 120 specimens that are talked about in your report.
You didn't perform an analysis of the number of nerves in each individual specimen of those 120 that you examined, in order to arrive at a range of averages of the number of branches ingrown into mesh structures for transvaginal mesh?
MR. ORENT: Objection.
THE WITNESS: I have done for large part of those. Those counts are done for large number of this specimens.
BY MS. BYARD:
Q. That doesn't appear in your report, does it?
A. Which, which report?
Q. In your report, Exhibit 197?
A. Which one? I don't understand.
Q. Or 196.
A. On the general report? As I said, it doesn't have diagnostic significance.
Q. So it wasn't done? That's my only

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question.
A. I've done it.
MR. ORENT: Objection.
THE WITNESS: You asked me if I've done it for 120. I've done the count for those which were completed cases.
I have stacks of cases at different stages of completion. It's work in progress for some of them. But with the cases completed, altogether with a surgical pathology report, there is count. For each single specimen completed, there is count of nerves and nerve densities.
BY MS. BYARD:
Q. And of the 25-plus cases we will talk about tomorrow, you have one example of that, right?
MR. ORENT: Objection. Misstates his testimony.
THE WITNESS: Not example. One case is completed in that respect.
BY MS. BYARD:
Q. Okay. And the range of the number of nerves ingrown into mesh structures for transvaginal mesh in the 120 specimens that are detailed in your report, doesn't appear in your

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report, does it?
MR. ORENT: Objection.
THE WITNESS: No, I didn't record it. Because I'm not basing my opinion for that specific -- for this specific purpose we are here today.
BY MS. BYARD:
Q. Okay. And, Doctor, if there are reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay?
You conclude this paragraph on page 803 of Exhibit 1197 by saying:
"These one to three ingrown nerves into the pores constituted a median of 6.3 percent range, 2.17 percent to 15.8 percent of all nerves seen within the examined tissue."
A. That's correct.
Q. Here you compared the number of nerves ingrown into pores with the number of nerves that were seen in the examined tissue as a whole?
A. Yes. I mean, so this is a percentage of those nerves which were seen ingrown, with those three criteria we discussed earlier.

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Q. And compared to the number of nerves that were in the examined tissue overall, the number of nerves that were grown into pores, was a median of 6.3 percent with a range of 2.17 to 15.8 percent, correct?

A. That's correct.

Q. Have you performed this same statistical analysis for the transvaginal mesh specimens?

A. For those I completed test, I mean, it's somewhere in the spreadsheet. I started testing that as well. But it's only when the nerve count is completed that I can do it.

Q. So it's not in your report, is it?

A. No. It has no diagnostic significance. One nerve is enough. I mean, if you have one nerve in the tooth and it hurts, it's just one nerve is enough.

MS. BYARD: Object and move to strike after the words, "No, it's not in the report."

MR. ORENT: Oppose.

BY MS. BYARD:

Q. Do you know how the percentage of nerve ingrowth in transvaginal mesh samples within mesh structures compares to the number of nerves in

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transvaginal mesh specimens overall?

MR. ORENT: Objection.

THE WITNESS: I think I answered that generally, density is about six times higher. I mean, it depends on how you group those devices. If you split them into slings versus POP devices, but generally several fold higher.

BY MS. BYARD:

Q. That's true across the tissue specimen, though, correct?

A. Transvaginal. If we compare transvaginal versus inguinal hernia, that's true.

Q. What I am focused on now is the amount of nerves growing into the mesh pores compared to the amount of nerves overall. And we know from your study that it's around 6.3 percent for inguinal hernia repair mesh.

I'm asking if you have a percentage for me of the percentage rate of nerve ingrowth into compartmentalized pores for transvaginal mesh as compared to the number of tissues overall in the specimens that you've examined?

MR. ORENT: Objection.

THE WITNESS: As I said, that work is not completed. It is not done yet. If there is a

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scientific question, I will complete it. But again, the conclusions in this paper were not based on this number. This number was provided for readers to understand what is going on.

BY MS. BYARD:

Q. Could you tell me, sitting here today, what percentage of nerves you would expect to be ingrown compared to not ingrown and present in tissue for transvaginal mesh?

A. At least the same as in hernia. As I said, likely several fold higher as well, because of difference in anatomical orientation.

As I said, in transvaginal location, there are branches that going to innervate mucosa, so they're perpendicular to the mesh. So I'm expecting to see much higher percentage.

Q. That's a working hypothesis at this point, but not a scientific conclusion arrived at through the same type of statistical analysis --

MR. ORENT: Objection.

BY MS. BYARD:

Q. -- right?

A. Yes, this is. But it will be at least 6.3 percent. Again, diagnostically, it's irrelevant. For specific patients, for specific

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purpose we're here today.

Q. And here you have this nerve assessment data Table 1 on page 804.

A. Yes.

Q. And the transvaginal specimen analysis that you have done, did you compare virgin tissue and scar tissue with actual samples?

A. No --

MR. ORENT: Objection.

THE WITNESS: -- I mean I don't understand why you're asking these questions. And I didn't complete -- this was different study and just, I mean, this is -- again, as I said, this is not diagnostically relevant.

MS. BYARD: Object and move to strike everything besides, "no."

MR. ORENT: So are you suggesting by your repeated motions to strike, that he's not entitled to give a full answer?

MS. BYARD: I don't think I have to answer your question for the basis of my motion.

I just -- my questions are simple, and we're going to be here a long time if I can't just get answers to my questions.

MR. ORENT: I think that's what he is

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doing. And I think you're going beyond the scope of what he's even intending to offer at trial. So if we stick to his opinions, we can move fast, too.

But, Doctor, you can go ahead and keep answering your questions as you see fit.

BY MS. BYARD:

Q. So here for this study, you've used control samples, haven't you?

A. For this study, yes.

Q. You used the control sample in virgin tissue?

MR. ORENT: Objection. Asked and answered.

THE WITNESS: Yes.

BY MS. BYARD:

Q. You used another control sample in scar tissue, correct?

MR. ORENT: Objection. Asked and answered.

THE WITNESS: Scar tissue was control and at the same time, it was a test group depending on how we compare them.

BY MS. BYARD:

Q. In your report on your 120 specimens for transvaginal mesh, you don't have a

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control group in virgin tissue?

A. This is research. This is diagnostic work. We are mixing things which are completely unmixable. I just don't understand why we are doing this.

Q. Please answer my question.

MR. ORENT: Objection. Asked and answered.

THE WITNESS: This is research. This is diagnostic work. Can you repeat the question so I understand what we are talking about, research or diagnosis?

MS. BYARD: Would you mind reading back my question, Madam Court Reporter?

REPORTER'S NOTE: Whereupon the question was read back as follows:

"In your report on your 120 specimens for transvaginal mesh, you don't have a control group in virgin tissue?"

MR. ORENT: Objection.

THE WITNESS: I do. There are samples in St. Michael's Hospital of transvaginal mucosa excised. So when the study is completed, I intend to examine those as well.

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BY MS. BYARD:

Q. That's not in your report?

A. That's for research, the report is diagnostic. Again, the same issue. We are mixing up unmixable things. Research and diagnostic work.

Q. That's not in your report is it, sir?

MR. ORENT: Objection.

THE WITNESS: There is no statistics of comparison at all, because my reports are diagnostic reports, and this is research.

BY MS. BYARD:

Q. So you agree with me it doesn't appear in your report?

MR. ORENT: Objection. Asked and answered for the fourth time.

THE WITNESS: There was no research methodology or -- the reports are not research project. They are reports.

BY MS. BYARD:

Q. So the answer to my question is, no, that control group in virgin tissue is not set forth or analyzed in your report in the litigation?

MR. ORENT: Objection.

THE WITNESS: It's not mentioned, but I

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know about the mesh tissue, or human body interactions based on this study.

So in order to produce this report, I used my knowledge, which I gained through my training, through this study and other studies, and then I make conclusions in diagnostic report. I could not put everything which I know or which -- or research studies I've done and the reports.

BY MS. BYARD:

Q. Have you done an analysis of nerve assessment data on vaginal virgin tissue?

MR. ORENT: Objection.

THE WITNESS: As I said, it's work in progress. It will be done when I complete.

BY MS. BYARD:

Q. To date, it hasn't been completed?

MR. ORENT: Objection.

THE WITNESS: No.

BY MS. BYARD:

Q. And the same thing is true for vaginal scar tissue, correct?

A. As I said, it was not a question for the reports. The reports describe pathological findings which I see, which I know pathological already.

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We're talking about research questions. Sometimes it's question which is not relevant specifically to diagnostic process.

Q. The answer to my question is that, no, that analysis has not been completed to date, right?

MR. ORENT: Objection.

THE WITNESS: The answer is, yes, I have not completed the analysis of transvaginal meshes for research purpose.

BY MS. BYARD:

Q. And I'm focusing on an analysis of vaginal scar tissue.

MR. ORENT: Is there a question there?

BY MS. BYARD:

Q. Same question for vaginal scar tissue.

MR. ORENT: Objection to form.

THE WITNESS: That, that's correct.

BY MS. BYARD:

Q. You write that you:

"Detected no indication that the scar around and within the mesh has significantly lower innervation than an ordinary scar." Correct?

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A. That's correct.

Q. Are those same findings true for transvaginal mesh?

A. As I said, I mean, we -- to answer these questions which are not relevant to diagnostic process, you would have to compare vaginal scar and the scar in around meshes.

Q. And that work has not been completed to date, correct?

A. It has not been completed.

Q. Based on your observations to date, do you expect that the innervation within a mesh scar conglomerate is the same as within vaginal scarring?

MR. ORENT: Can you repeat that or read that one back?

REPORTER'S NOTE: Whereupon, the pending question was read back as follows:

"Based on your observations to date, do you expect that the innervation within a mesh scare conglomerate is the same within vaginal scarring?"

MS. BYARD: Let me add to that.

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BY MS. BYARD:

Q. In terms of the number of nerves present in tissue specimens density?

A. My expectation is that the scar outside of the mesh would have about the same nerve density as an irregular scar from after any procedure.

In regards to innervation inside the mesh, it will be somewhat lower than innervation outside. But again, it's not clinically relevant because the fact that it can ingrow, that's the most important clinical question.

Q. And again, whether or not the number of nerves that ingrow at the mesh is lower, or whether it's statistically significantly lower, is an open hypothesis at this point, true?

MR. ORENT: Objection.

THE WITNESS: I don't understand why we are asking this. I mean, diagnostic process is --

BY MS. BYARD:

Q. Sir, you don't need to agree with my questions or why I'm asking them --

MR. ORENT: Excuse me. He's answer --

BY MS. BYARD:

Q. -- you just need to answer them.

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MR. ORENT: Counsel, he's entitled to finish. The way this process works is, you ask a question, he answers. You don't cut him off midway through his answer.

He's entitled to finish his answer, then you can say whatever you want to say.

Doctor?

MS. BYARD: If you wouldn't mind, Counsel, I think it would be productive for you to provide some guidance to the witness about not disputing why I'm asking a question.

MR. ORENT: Well, if he doesn't understand, I think he's trying to understand where this fits and so that he can answer the question. I don't think he's trying to be difficult.

But, Doctor, if you could answer.

THE WITNESS: So my response is because as far as I understand, we're talking about the conclusions I derived based on my training, knowledge, experience and the research included in this one.

But it appears that you equate research with the diagnostic process. Whatever I have done in this study was in my head before I looked at these specimens.

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BY MS. BYARD:
Q. And I'm trying to understand what you've done on hernia repair and what you've done on transvaginal mesh, okay?
A. Okay.
Q. And at this point, whether or not the rate of nerve growth within transvaginal mesh is less than the rate of nerve growth in the scar surrounding the mesh is an open hypothesis, correct?
MR. ORENT: Objection.
THE WITNESS: I can tell you that I have some initial data, initial observations, but it's not completed. Statistics is not completed yet.
BY MS. BYARD:
Q. Okay. Thank you, sir.
Just to paraphrase, your findings with respect to hernia repair was that both scar tissue and scar tissue with mesh have a higher number of nerves than virgin tissue, but that the difference between the two groups was not statistically significant? That's correct?
A. (Witness nods.)
Q. Now, if you look at the last

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paragraph of the result section, which is just before "discussion," you measured the nerves that you saw, right? And by that I mean, you measured their size?
A. Diameter, yes.
Q. For your evaluation of transvaginal mesh specimens, you didn't measure the diameter of the nerves that you detected, did you?
A. No.
Q. Part of what you were doing here in your study with Dr. Bendavid, was trying to correlate the size of the diameter of the nerves that you found to whether they were similar, dissimilar to inguinal or iliohypogastric nerves, correct?
A. No.
Q. Tell me what you were trying to do by measuring the diameter of the nerves then?
A. What I've just described, so the readers would understand what I'm talking about. Had no diagnostic significance.
Q. Well, you write:
"At 0.9 millimeters, the size is not too dissimilar from that of the ilioinguinal or iliohypogastric

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nerves." Correct?
A. That's correct. That's a statement. It has no diagnostic conclusion or anything else.
Q. Why did you include that language?
A. As I said, it's a description of what we see, just for readers to understand what's going on under the microscope.
Q. There are clinicians who contributed to this paper, right?
A. Yes.
Q. Is it possible that to Dr. Bendavid or to Dr. Koch, that whether these were similar in size to ilioinguinal or iliohypogastric nerves had some clinical bearing?
MR. ORENT: Objection. Calls for speculation.
THE WITNESS: Had no clinical bearing.
BY MS. BYARD:
Q. Did you write this sentence or did they?
MR. ORENT: Objection.
THE WITNESS: Oh, their manuscript was edited, rewritten several times, several people contributed.

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I certainly contributed to each sentence in one way or another. And I measured. Nobody else could measure them.
BY MS. BYARD:
Q. Are you the one who supplied the information about how the nerve sizes and diameter compared to the size of known nerves in this particular anatomy?
A. This is comparison of microscopic. So I contributed by microscopic what I see, and clinicians contributed to what they can see with bare eyes without the microscope.
So the comparison is, roughly, for surgeons to understand that the nerves we are talking about can be as big as those they can see by naked eye, but they can be much smaller that they cannot see them. Therefore, they cannot avoid them.
So basically it leads to readers to understand that it's unavoidable to damage nerves because they are so small that surgeons cannot see them.
Q. And it was important for the surgeons to talk about the type of nerves that these were similar in size to, correct?

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MR. ORENT: Objection.
THE WITNESS: I don't understand the question. What do you mean, "type of nerves"?
BY MS. BYARD:
Q. Well, it mentions specifically inguinal and iliohypogastric nerves, doesn't it?
A. It's not a type of nerve. It's just a name of a larger branch.
Q. Here, that name of those branches was important to specify?
A. No.
Q. It was completely superfluous?
MR. ORENT: Objection. Argumentative.
THE WITNESS: This is something which surgeons have readily -- are familiar with. It's a comparison, it's like a sliding scale, from 1 to 10. So everybody within the span would know what we're talking about.
BY MS. BYARD:
Q. You're not a pain specialist, right?
A. What do you mean "pain specialist"?
Q. You don't treat and manage pelvic pain, do you?

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A. That's correct.
Q. And you're not a neurologist?
A. No, I am not a neurologist. You know what I am, I am pathologist.
Q. And you're not a specialist in sexual health, correct?
A. I just answered, I'm a pathologist.
Q. Let's look at the discussion, please. You describe here that:
"Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance."
A. Yes, that was mostly Dr. Bendavid's contribution in this part.
Q. I like his writing style.
A. English is not my first language, so he writes better than me.
Q. He writes:
"A mini-revival took place with the rediscovery of --"
And then he names some researchers and surgeons, right?
A. That's correct.
Q. And he writes:

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"-- for a better understanding and application of anatomy, which easily transferred to tension free and laparoscopic repairs." Right?
A. That's correct.
Q. He writes:
"Today's leitmotif in hernia surgery, to accompany the newer techniques, has been the extensive use of prosthetic materials."
A. That's correct. That's epidemics now.
Q. He used -- he says:
"The philosophy of tension free repair which was made possible by the advent of synthetic materials was born in Marseille, France, fathered by Don Aqauviva in 1944, who used sagittate nylon sheets as an onlay over a defect which itself was left intact."
Did I read that correctly?
A. Yeah, you read it correctly.
Q. He says:
"The theme was re-visited by

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Henri Fruchaud in 1956, who designed an operation also using nylon mesh in a manner which was antedated and precisely anticipated Francis Usher."
Did I read that correctly?
A. Yes, it appears you read it correctly.
Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique."
Did I read that correctly?
A. That's correct.
Q. And then it continues that -- in this next full paragraph:
"While several surgical techniques based on the principles of tension free repairs have been introduced in the last 30 years, polypropylene has become the dominant olefin utilized to that end."
Did I read that correctly?
A. That's correct.
Q. It goes on to discuss the plastics industry producing Marlex; do you see that?

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A. Yes.
Q. And a synthetic polymer discovered by J. Paul Hogan and Robert Banks of the Phillips Petroleum Company; do you see that?
A. I lost you. Yes, I do see that.
Q. And it says:
"This discovery was made possible, thanks to the pioneering work and olefin chemistry by two Nobel Prize laureates 1963, Giulio Natta and Karl Ziegler."
Do you see that?
MR. ORENT: Objection.
THE WITNESS: That's correct.
BY MS. BYARD:
Q. And then it goes on to describe there being an "unexpected and unpredicted prominence of pain" being the most common complication seen in mesh groin hernia repairs today, doesn't it?
A. That's correct.
Q. There's a discussion then about the industry development of lighter mesh, meshes with larger pores. Do you see that?
A. Yes.

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Q. And it essentially then describes this, this tradeoff in terms of collagen versus scar tissue ingrowth?
A. You would have to read the sentence to me.
Q. Sure. I just, I would hope to summarize. Essentially here, and correct me if I don't get this accurately, but essentially here you go on then to describe there being tradeoffs between wider pore -- lighter, larger pore meshes and smaller pore heavier weight meshes, correct?
MR. ORENT: Objection.
THE WITNESS: Yeah, we discussed that topic.
BY MS. BYARD:
Q. Sure. And then it says:
"To understand the complex interaction between the olefins and biological tissues, their site of contact needs to be studied as a compartmentalized living tissue."
A. That's correct.
Q. "Additionally, tissue forces and chemical environments affect the mesh which in turn may have an

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effect on tissue components."
That's what's written here in your article, right?
A. That's correct.
Q. In this sentence you don't write that "tissue forces and chemical environment affect the mesh, which in turn has an effect on tissue components," do you?
A. I have to see the sentence.
MR. ORENT: Where is the sentence you're looking at, at this point?
MS. BYARD: It's the first sentence preceding the discussion of Figure A and Figure B.
THE WITNESS: Oh, this is like a feedback, this is a description. See, first is description that mesh affects, and then there is effect. And then there is a tissue which is affecting mesh, and but mesh can react back, so it's a complex sort of mechanism, which he has not studied yet.
BY MS. BYARD:
Q. And the stage that you're at here with hernia mesh, is understanding the tissue response to mesh, right?
MR. ORENT: Objection.

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THE WITNESS: It's hard to actually differentiate what is mesh response to tissue, or tissue response to mesh, or what is mesh effect on the tissue, or what is tissue reaction to the mesh. I mean, it's interaction between mesh and tissue.
But the intricate details of how this feeds back and catalyzes the process, I have not studied. Molecular mechanisms.
BY MS. BYARD:
Q. And the same is true for transvaginal mesh, true?
MR. ORENT: Objection.
THE WITNESS: That's correct. We can see the changes, what is the end result. But how this is all happening, and through what molecules, and this is not studied yet.
BY MS. BYARD:
Q. If you turn to page 808, please.
A. Yes.
Q. There is a discussion of you all setting up a mesh retrieval industry; do you see that?
A. Yes.
Q. And there being a protocol developed to address how contributions are made to

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the registry?
A. Not exactly. Not how contributions are made. Dr. Bendavid through his contacts with colleagues, I mean, we started acquiring meshes just to build a library of specimens and examine them.
Q. And then it says:
"The next step will be the correlation of histology/pathology to the clinical presentation and severity of pain."
A. Yes, that's correct.
Q. What will your role be in this registry as far as you understand it?
A. Not will be, I'm collecting specimens, I'm examining them.
Q. Is your job to do the correlation of the histology pathology to the clinical presentation and severity of pain?
A. Yes. I mean, I examine these specimens, There is history in them. Statistician is involved, so she's Dr. Lou is doing final statistical analysis. So statistical tests are applied by her. I do some statistics as well on the go and...

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Q. Who's the one evaluating the clinical presentation severity of pain for this registry, though?
A. Mostly treating clinicians, so they provide -- I mean, at this stage what we manage to do is separate specimens according to reason for excision.
So if pain is severe enough to cause excision without any other factors, or if pain was contributing factor as a reason for excision, assuming there is a combination of pain and hernia reoccurrence. Or, when the pain either didn't exist, or pain was low enough not to trigger incision, but mesh was either excised or sampled during revision of hernia reoccurrence. So that's where we ended up. I mean, so severity of pain became assessed as a reason for excision.
Q. Okay. And that's done by the treating physician, correct?
A. Yes.
Q. And then the correlation between the pathology, what you find under microscopic examination, and this clinical presentation, severity of pain, who does that job?
A. Initially, I see it. I mean,

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after I examine the specimens, then they are all put in all table, and then I can see the difference. But final statistical analysis is done by Dr. Lou, she does statistical tests.
Q. So she's inputting the reasons for the excision, the clinical presentation, severity of the pain, she's inputting that with your histological findings?
MR. ORENT: Objection.
THE WITNESS: No. I'm receiving the specimens, I'm receiving initial information with the specimens.
BY MS. BYARD:
Q. What initial information?
A. Reason for excision. I'm collecting age, gender, heterology, type of hernia, is it ventral, is it molecular, is it inguinal, I'm collecting all this clinical information with the specimen. It comes with specimens.
Q. You conclude this paragraph by writing:
"This is the duty of our profession. It is an oath" -- I'm sorry. I didn't start soon enough. Let me strike all that.

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You write:
"While knowledge comes, let us translate it into wise application for which it was meant. This is the duty of our profession, it is an oath which we must honor proudly, disconnected from any notions of personal or commercial conflicts of interest."
Do you agree with those statements?
THE WITNESS: Yes, I do.
BY MS. BYARD:
Q. Here in the conclusion, and we had started to talk about this in the abstract, and so I wanted to return to it because you had pointed me that further on in the paper there would be discussion of it. So let's look at that.
You write in the conclusion:
"It is felt that the mechanism of pain associated with the use of mesh may similarly be due to micro entrapment and micro compartment types of syndromes through new nerve and vessel ingrowth within the mesh pores and other confining spaces

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with the concomitant edema, anoxia, thrombi scarring, distortion, migration and traction."
THE WITNESS: That is correct.
BY MS. BYARD:
Q. Do you see that?
A. That's correct.
Q. And is that what you were referring me back to when we were talking about the abstract?
A. Yes.
Q. Again, you say that:
"It is felt that the mechanism of pain associated with the use of mesh may be due to micro entrapment and micro compartment." Right?
A. It says "similarly."
Q. So the analogy that you're making --
A. So the mechanism is similarly. Not that it's due or not due. The "may" implies a similarity.
Q. Between what and what?
A. Yes.
Q. Between what and what?
A. Between compartment syndromes we

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already know, and these new compartment syndromes we just discovered.
Q. So the mechanism of pain is understood for compartment syndromes that are already established?
A. Yes.
Q. And the mechanism of pain associated with mesh may be similar for compartment syndromes that you're beginning to study here?
A. Yeah. Mechanisms may not be exactly the same, but may be similar. Likely to be similar.
Q. Because at this point in the study of hernia repair, those mechanisms of pain are not established yet?
MR. ORENT: Objection.
BY MS. BYARD:
Q. Right?
A. Details of the mechanisms. So when we observe the changes in the mesh, we clearly saw that the scar tissue within the mesh is not normal scar tissue.
So we knew that this tissue is innervated, because we saw nerve ingrowth, and we saw that it's not regular scar tissue. So the

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findings are there.
The balance of them, the details and everything else, again, is not studied, it needs to be further studied. But the findings, the abnormality is visibile, it's there. It's 100 percent there.
Q. So the -- you have observed and established tissue abnormalities with hernia mesh, right?
A. Yes.
Q. The step that hasn't been done yet is understanding the mechanism by which those tissue abnormalities lead to clinical complications of pain?
A. Yes. Details of those mechanisms.
Q. And with respect to transvaginal mesh, you're one step behind the study in that you haven't yet done the statistical analysis of relative rates of nerve ingrowth and compartmentalization?
MR. ORENT: Objection.
THE WITNESS: What do you mean, one step behind or in front?
BY MS. BYARD:
Q. Well, this study, this statistical

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analysis has been done. That statistical analysis is yet to be done for transvaginal mesh?
MR. ORENT: Objection.
THE WITNESS: Are you asking in respect of my opinions, or in respect of research and plans for research?
BY MS. BYARD:
Q. I'm talking about the body of scientific knowledge that's available. This was a contribution to the understanding of the tissue response to --
A. Yes, I understand that.
Q. -- to hernia repair?
A. Are you asking if this analysis was done to derive to the conclusions of this report, or are we talking just hypotheticals scientific questions.
MR. ORENT: Perhaps you can rephrase the question.
BY MS. BYARD:
Q. Okay. Let me try and do that.
And I only am trying to say that with respect to hernia repair, you understand you've identified abnormalities in the tissue, in mesh?
A. Yes. And this exactly the same in

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transvaginal meshes.
Q. You've identified tissue abnormalities?
A. Even more. I found more in transvaginal meshes than in what is the hernia meshes.
Q. Okay.
A. So in this respect, this part is step ahead from this.
Q. Well, in terms of the degree of abnormalities, you're saying?
MR. ORENT: Objection.
THE WITNESS: Yes.
BY MS. BYARD:
Q. Okay.
A. There are way more findings in transvaginal meshes than in hernia meshes. This study was specifically focused on nerve ingrowth. What we found there, abnormality in the scar tissue was observation only, sort of, on the way we did the study.
This was done later, and there are more findings, more abnormalities in transvaginal meshes.
Q. You've gotten to the level, though, of doing a statistical analysis to quantify

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the tissue abnormalities for hernia mesh?
A. Yes.
Q. And you haven't reached that stage yet for transvaginal mesh?
MR. ORENT: Objection.
THE WITNESS: Well, it's present. Whatever is present here is 100 percent. I see abnormality, it's stated there.
These rate and frequencies and everything else, only makes sense for scientific questions.
But for detection of abnormality in the specific specimen or specific patient, is 100 percent. I see it or I don't see it. If I don't see it, I don't describe it.
BY MS. BYARD:
Q. Okay.
A. We are talking about this specific reports which are produced for each specific patient, and this was done for actually one specific scientific question.
Q. And I guess I'm operating off the assumption that you've applied the same level of scientific rigor, that you did in this publication that you did with Dr. Bendavid, that you did for

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Exhibit 1196?
A. It's not scientific rigor or scientific work. This is diagnostic work; this is scientific work. This is research; this is diagnostic. When I see abnormal, I state. Here is a specific question.
I mean, you're just trying to mix things which are not -- not the same.
Q. But you've made conclusions in your report on transvaginal mesh that are broader than the conclusions that you've reached in this study?
A. Yes.
MR. ORENT: Objection.
BY MS. BYARD:
Q. Right?
MR. ORENT: Point out a particular question if you have one.
THE WITNESS: This part -- okay.
BY MS. BYARD:
Q. Go ahead.
A. No.
MR. ORENT: Wait for a proper question.
MS. BYARD: Are you instructing him not to answer that question?

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MR. ORENT: No. I think there's no question pending that's intelligible.
All you said is, "there are some opinions in here that are broader than those." But you haven't identified any opinions for him to address specifically.
BY MS. BYARD:
Q. Do you agree with what I've said, sir?
MR. ORENT: Objection.
THE WITNESS: Opinions or -- I'm a little bit confused. I mean --
BY MS. BYARD:
Q. Okay. That's okay, I can rephrase it.
So here in your study with Dr. Bendavid on hernia mesh, you've described what the mechanisms of pain may be for the relationship between tissue abnormalities and clinical complications, right?
MR. ORENT: Objection.
THE WITNESS: Details of this mechanisms, the connection. I mean, I see -- so, we know that there is reason for excision, we know that there are pathological findings. What we see in the microscope is not normal, it's abnormal.
We know that the mesh caused clinical

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symptom, had to be excised. How this all happened in small details, up to very small molecules of how they interact, is not known.

But we know the effect, and we know the pathological findings behind it. But the details of this connection, these small sort of details are not clear.

Some of it is, as mentioned, are similar to more study there is, like toothache I said, or heart attack. But again, this is in pieces.

BY MS. BYARD:

Q. So, for instance, you could have a nerve that was grown into scar tissue, that doesn't cause so much pain that the scar tissue has to be excised, right?

MR. ORENT: Objection.

THE WITNESS: This can happen. I mean, it may or may not. People are different.

BY MS. BYARD:

Q. And so you can look at a slide of mesh, with scar tissue, and see a nerve grown into it, and you can't predict whether that patient had pain, can you?

A. I can say that there is

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probability, there is mechanism for pain in that specific, if patient have or didn't have pain, this may depend on different circumstances. It may not hurt today, but it has probability it may hurt tomorrow.

So this would be, again, complex. And it's not just for a nerve. If there is a nerve ingrown in the tissue, it means that the tissue is alive. It can sense pain. So this is the baseline. Then, pain can occur at any time there. You add extra stimuli for pain, damage to the tissue, inflammation, edema -- the more you add, the probability goes higher and higher. But, again, you may have just a nerve ingrowth and it gets tugged, and you have mechanism of pain right away. So this is so complex, and a variable between people, we cannot apply a specific -- now I'm --

Q. It's not predictable?

MR. ORENT: Objection.

THE WITNESS: No, this is not true. It's predictable. If you have nerve ingrowth, you have baseline for pain development.

So, once you have innervation of the tissue, pain can develop. If you don't have

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innervation of the tissue, the tissue would not sense any pain. So this is, this is predictable.

If we have inflammation, we know that there will be lower threshold for pain. This has been studied extensively in other areas of inflammation. Inflammation is always associated with lower threshold of pain. What doesn't hurt in normal tissue, may hurt in inflamed tissue.

So inflammation is high enough, it will cause pain on its own. Inflammation itself will be enough to cause pain, but it may not be enough, and then it will need the extra stimulus such as edema. This is very complex interaction.

BY MS. BYARD:

Q. And so -- but those specific mechanisms of how this relationship between nerve ingrowth or vascular ingrowth, scar tissue, inflammation, and whether or not that will cause or predict pain in a patient is not yet described?

MR. ORENT: Objection.

THE WITNESS: It is described in other areas. It's a general knowledge of what they accumulated. I mean, does inflamed knee hurt? I mean, what do you think? It's not just described, it is a general knowledge. Something is inflamed,

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it may hurt.

BY MS. BYARD:

Q. Do you know whether 100 percent of patients with edema present in their mesh and the tissues surrounding their mesh will feel pain?

A. What's percentage of those who have edema or don't have edema? I don't know exact percentage. And I don't think it matters, because it might be multiple mechanisms.

So their pathological findings which are normal, and the degree of their contribution to pain development is hard to predict because it's so complex.

Q. And not yet known?

MR. ORENT: Objection.

THE WITNESS: What do you mean, "not yet known?" We know that inflamed tissue hurts.

BY MS. BYARD:

Q. But the rates at which it will occur -- for instance, with edema, you can't tell me the rates at which pain will occur or --

A. The main question is, it can happen. If it happens in the patient, you know why this is happening. Assuming, if an area in the body hurts, and you take a biopsy, and you see

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inflammation in there, but you don't see anything else, what would be your logical conclusion, why did it hurt? Because it was inflamed and you don't see anything else.

The same with meshes. Meshes hurt; they come out. There is no tumor in it, there is no informal carcinoma, but there is nerve ingrowth, there is mesh, there is scarring.

Therefore, the only reason for it to hurt is mesh-related changes. But the degree of contribution of how much inflammation contributed, how much edema contributed, is difficult to predict. It has been studied in other areas. It was not studied in specific details in meshes.

Q. Thank you.

Let me check the time.

MS. BYARD: Do you guys have steam for another article before we break for lunch?

THE WITNESS: I have to go to the washroom.

MR. ORENT: Why don't we take five.

THE VIDEOGRAPHER: Off the record at 12:24 p.m.

-- RECESS AT 12:24 --

-- UPON RESUMING AT 12:40 --

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THE VIDEOGRAPHER: We're back on the record at 12:40 p.m.

BY MS. BYARD:

Q. Doctor, would you agree with me that it's important to keep bias out of scientific research?

MR. ORENT: Objection.

THE WITNESS: Yes. Yes, it is important.

BY MS. BYARD:

Q. And you would agree that bias in the form of industry influence, is bad for science, right?

MR. ORENT: Objection.

THE WITNESS: Yes.

BY MS. BYARD:

Q. So if a study was supported or funded by industry, the author would disclose that, right?

A. Yes, usually all conflicts are disclosed.

Q. Or should, in your view --

A. Should, yes.

Q. -- disclose that?

A. Yes, yes. Sometimes there's so

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many points of contact with other agencies, not everything is disclosed, or authors decide for that specific study there is no conflict of interest. It's more up to the discretion of the author.

Q. But all things being equal, the better course would be if the bias might affect the subject of study, to disclose that conflict of interest, right?

A. Yes --

MR. ORENT: Objection.

THE WITNESS: -- it's the best sort of scientific practice. Not practice, but --

BY MS. BYARD:

Q. It's important for authors in the scientific and medical community, to disclose conflict of interest?

MR. ORENT: Objection.

THE WITNESS: It's important for readers to know if there's potential conflict of interest, yes.

BY MS. BYARD:

Q. So, at this point, you have been deposed, I think we had the number at around seven or eight times in litigation where you've testified as an expert against mesh manufacturers, right?

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A. That's correct.

Q. And you've never once testified for a defendant manufacturer in a medical device case, correct?

A. You mean like crossing sides? No.

Q. You never testified on behalf of a mesh manufacturer in that company's defence?

MR. ORENT: Objection.

THE WITNESS: No.

BY MS. BYARD:

Q. And since 2012, early 2013, all of the work that you've done on mesh as an expert in litigation has been for plaintiffs, right?

MR. ORENT: Objection.

THE WITNESS: That's correct. It just happened that all findings I had, they were supporting plaintiffs' claims.

BY MS. BYARD:

Q. Those findings were made while you were being paid for your work for the plaintiffs' though, correct?

MR. ORENT: Objection.

THE WITNESS: I'm just paid for my time.

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BY MS. BYARD:
Q. You're paid by plaintiffs for your time?
MR. ORENT: Objection.
THE WITNESS: Sometimes, like today, I don't know, maybe you will pay for that, I mean -- I actually sometimes don't know where the money comes from. There's so many people involved.
BY MS. BYARD:
Q. And while there's nothing -- I guess returning to my question about disclosures. There's nothing that prevents an author from providing disclosures of conflicts of interest if the author feels that's important, right?
A. For full articles, it's usually a requirement, but sometimes for abstracts, I mean, then you don't know where to squeeze it, if there is no line when you submit it. So for abstracts there may be no space to put this disclosure.
So if I don't have that space, while submitting an abstract, I insert a slide disclosing that I've been consulting for medical-legal cases. I don't remember single time when I never -- when I have not disclosed it.
Either way, I will find a way how to

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disclose it. Either during presentation or during abstract submission, or any other way.
Q. Were all the publications that you have authored on transvaginal mesh published in 2014?
A. Yes.
Q. And the articles that you've authored on transvaginal mesh have direct bearing on the reasons for your opinions in the lawsuit, right?
MR. ORENT: Objection to form.
THE WITNESS: It's kind of -- I wouldn't word it like this. I considered all the knowledge extracted during, doing this research project in formulating my opinions in these reports, yes.
BY MS. BYARD:
Q. Well, and in fact, in all of the publications that you authored, that came out this year, you included information that you identified during your work as a paid expert for the Plaintiffs, correct?
A. Yes. As I said, I mean, I disclose it every time I can.
Q. Let's mark 1198.

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A. Payment is not the only bias, I will mean only other bias. I mean it's just what you consider. But people may be biased by something else.
EXHIBIT NO. 1198: International Scholarly and Scientific Research & Innovation, 2014, Publication entitled, "Pathology of Explanted Transvaginal Meshes," by Dr. V. Iakovlev, Dr. E. T. Carey and Dr. J. Steege.
BY MS. BYARD:
Q. Doctor, do you recognize Exhibit 1198?
A. Yes, it's a paper I co-authored.
Q. Dr. Erin Teeter Carey is an expert whose time is paid for by the Plaintiffs in the mesh litigation; isn't she?
A. Yes.
Q. And Dr. John Steege is a paid Plaintiffs' expert too, right?
A. Yes.
Q. And you were in fact introduced to Dr. Erin Teeter Carey and Dr. John Steege by Margaret Thomson, a lawyer for the Plaintiffs, right?

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A. Yeah. I think first contact was during a conference call, and I think Dr. Thomson was either participant or organizer of that call.
Q. She was acting as a lawyer during that conference call, correct?
MR. ORENT: Objection. At this point, I'm going to instruct the witness not to answer to the extent that there are -- that this was as part of a case consultation or work.
You can answer to the extent that you had any conversations with the four of those people related to non-litigation work.
BY MS. BYARD:
Q. Dr. Margaret Thomson was on the call in her capacity as a lawyer, not in her capacity as a medical doctor, right?
MR. ORENT: Objection.
THE WITNESS: I don't know. She's a doctor and a lawyer, I mean, what capacity she's serving in...
BY MS. BYARD:
Q. You were paid for your time on these conference calls by Plaintiffs' lawyers or their firms, right?
MR. ORENT: Objection.

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THE WITNESS: I don't think I specifically charged for all these conference calls or contacts. It depends, I mean, it's...

BY MS. BYARD:

Q. You weren't there in conjunction with your work as an anatomical pathologist at St. Michael's, though, right?

MR. ORENT: I'm going to now instruct the witness -- this is all covered by Rule 26 privileges. So if you want to ask questions related to his work on these papers, I'll let him answer anything related to the papers. But if you're asking about his specific relationship with Plaintiffs, Plaintiffs' experts and trial strategy meetings, I'm going to specifically instruct him not to answer.

BY MS. BYARD:

Q. Are you going to follow Counsel's instruction?

A. As I said initially, I had first contact --

MR. ORENT: I only want you to answer as to the extent that you can answer without revealing any trial strategy meetings you may have attended, or anything related to your consultation

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related to Plaintiffs in this litigation.

THE WITNESS: Okay.

BY MS. BYARD:

Q. Let's take a look at the abstract of this published article conceived in a conference call with Plaintiffs' counsel.

MR. ORENT: And I'm going move to strike that comment as without foundation.

BY MS. BYARD:

Q. It says:

"We aimed to perform a thorough pathological examination of explanted POP meshes and describe findings that may explain mechanisms of complications resulting in product excision."

Do you see that?

THE WITNESS: Yes, I do.

BY MS. BYARD:

Q. And again, we see that word "may" there, don't we?

A. Yes. This is a commonly accepted term, which we use when the degree of significance is not 95 percent.

Q. So the degree of confidence or

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significance? I didn't hear you.

A. The degree of statistical significance is not either assessed, or is not 95 percent, or there are other factors which introduce the degree of unknown factors.

Q. Okay. So here, for whether or not the pathological examination explains mechanisms of complications resulting in product excision, which one of those factual scenarios that you described applied? Is that, is it that there was not an assessment of statistical significance? Was it that there was other confounding factors, or that the degree of significance was not statistically -- the degree of difference was not statistically significant?

MR. ORENT: Objection.

THE WITNESS: No, neither. Because this states a hypothesis, so before we started, we examined and we had a hypothesis made. So it was -- this statement describes state of the research project before the research project.

BY MS. BYARD:

Q. Okay. So let's look at the discussion on page 508. The last paragraph of the discussion ends after discussion of nerve

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entrapment and compression, stretching, edema, ischemia.

It says: "The roles of these mechanisms need to be further studied," doesn't it?

A. Yes. Exactly which part of -- can you point?

Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under "Discussion".

A. Yes, I can see it.

Q. And I read that correctly, right?

A. "The roles of these mechanisms need to be further studied." Yes, that is correct.

Q. The conclusory sentences of the next paragraph read:

"Polypropylene degradation may play a role in the continuous inflammatory response mesh hardening and light deformations."

Did I read that correctly?

THE WITNESS: That's correct.

BY MS. BYARD:

Q. And it says:

"Also, chemical products of degradation need to be studied for

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their composition and effect on the tissue."
Did I read that correctly?
A. That is correct.
Q. And then in the last sentence of the last paragraph of the discussion, it says:
"We believe that these specimens contain information of the mechanisms of complications and further study may help guide future development of treatment modalities."
Did I read that correctly?
A. That's correct.
Q. And it says:
"These are previously unreported findings."
In the first sentence of that paragraph, right?
A. Some of the findings were previously unreported, yes, that's correct.
Q. And again, was this language "may" used here because the statistical -- a statistically significant difference was not assessed between controlled samples in the study?
MR. ORENT: Objection.

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THE WITNESS: You have to point exact sentence. Which, which "may"?
BY MS. BYARD:
Q. "Polypropylene degradation may play a role in the continuous inflammatory response, mesh hardening and late deformations."
A. Yes, so let me see. I have to read the whole paragraph.
Q. Okay.
A. (Witness reviews document).
Yeah, this is a combination. See, inflammatory response, mesh hardening and late deformations.
This is observations which we have. But the degree of connection between degradation and each of this is different.
For example, if we go to continuous inflammatory response, we would have to study exact chemicals which are produced during degradation. And how these chemicals may modify inflammatory response and other thing, this is unknown. Therefore, it introduces a degree of uncertainty.
Mesh hardening -- there will be different mechanisms for mesh hardening, scar

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ingrowth, then degradation itself, how much of one of those contribute and so on. It's, again, degree of uncertainty.
Also, degradation is continuous process, so it will build up over the years, in the beginning so -- there's a degree of uncertainty between all of those. I mean, what we know, it degrades, and with what we know, it hardens. So these are the two points which we know for sure.
But the degree of connection and the complex interaction between these factors is not studied to details. Therefore, in scientific literature the word "may" is used.
Q. What this discussion doesn't say is that the tissue findings that you have observed in transvaginal mesh causes pain through the mechanisms that you've described?
A. Where does it say?
Q. Well, I'm saying, nowhere does this discussion conclude that, does it?
A. It wasn't the purpose of the study. Just read the title: "Pathology of Explanted Transvaginal Meshes."
It was a descriptive study describing the findings.

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Q. Okay. And, again, this article doesn't even go so far as to say that mesh could cause pain through the -- through these tissue response mechanisms that you've described?
MR. ORENT: Objection.
THE WITNESS: Again, this was not the purpose of this study. Purpose of this study, if you read the abstract is, meshes cause complications. This triggers excision, and they have not been studied as to find reasons and mechanisms of the complications.
So the purpose of this was to study and see what is pathological in those specimens, abnormal. And then these abnormalities can be described and documented.
And then the next step would be to split specimens according to specific complications and see statistically what each of those specific pathology co findings contribute, and what's the interaction between them. So it's study details of all this.
BY MS. BYARD:
Q. And that second step that you've described wasn't done here?
A. No.

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Q. And it hasn't been done by you?
A. I'm in the process of doing, studying the small details of these things.
Because for each specific finding, there is a degree of knowledge we have in pathology and overall in general. I mean, even for common person, if vessel is obstructed, you know, there will be no bleed going through it. It doesn't need further studying.
But how does it get obstructed? Is it because there is a slowing down of the blood in there? Or because it's chemical issues affecting -- a chemical product of degradation, which is affecting blood or blood vessel, that makes it clot.
All these details will have to be studied. I'm surprised it wasn't for 50 years, because the findings are there.
Q. Right, and that's a fair point. I mean, for 50 years, pathologists have looked at polypropylene mesh, and no one has seen what you have seen and reported here, which is degradation --
MR. ORENT: Objection.
BY MS. BYARD:

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Q. -- right?
A. Have they been looking at all meshes? Have they been looking to answer the questions of complications? I mean...
Q. My question is simpler: No one else has reported having seen what you see.
MR. ORENT: Objection. That misstates the record.
THE WITNESS: That's not true. I mean, there are papers which are stating some of the findings.
Like polypropylene degradation, it was first described in the '70s. There's a degree, there are different methods. Sometimes it's not the primary purpose of the study, but in combination, these findings were mentioned in many papers.
BY MS. BYARD:
Q. By pathologists?
A. Pathologists -- you mean scientist pathologists or diagnostic pathologists?
Q. Either.
A. I don't know. We would have to look at each paper and see what's the credentials included, and what exactly is described there.

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Q. Okay. We can do that in a second.
Looking back here at the "Materials and Methods Section," if you would, Doctor.
A. Yes.
Q. You write:
"In total, 24 specimens of St. Michael's Hospital patients and external consultation cases from litigation processes have been analyzed."
Did I read that correctly?
A. That's correct.
Q. What does, "external consultation cases from litigation processes" mean?
A. Litigation cases.
Q. These lawsuits we're here to talk about today, as well as the ones involving other manufacturers?
A. Yes.
Q. Why is the number here 24, when we -- in your report we have 120?
A. For that specific number -- first of all, let's see if it was -- see, it was limited to POP first. It was limited to those -- I could get exact information at that point, it was entered

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in the spreadsheet. So at that point, I had verified reliable data, which was on the spreadsheet for those 24 only POPs.
Again, this was started much earlier before 120. The paper became published maybe half a year after the study was pretty much done.
Q. So at the time that you submitted this report for publication, you only had the completed verified data set or 24 POP specimens; is that right?
MR. ORENT: Objection.
THE WITNESS: With all information, I would need to include it in the study, yes. It my be for some samples I didn't have exact information if it was POP or sling or something else.
BY MS. BYARD:
Q. If we were going to consider the 120 specimens that are in your report for inclusion in this study, how many would meet the criteria?
And let's say for purposes of this evaluation, that the study is not limited to POP, but includes SUI product?
MR. ORENT: I just want to object to your use of the term, "120 cases included in your report."

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I want to make clear, what Dr. Iakovlev is talking about on page 2 of his report is his experience, and then he goes on to talk about his education and training.

His opinions are based on his experience, education and training; but are not based specifically on any one sample or samples. And I think you're confusing him. It's not a report on 120 cases that he's offered here.

MS. BYARD: Counsel, again, the speaking objections are not --

MR. ORENT: That's not an objection. That's a clarification for the record.

MS. BYARD: I'm asking him about his data set, which are specimens, which are what my questions are directed to.

THE WITNESS: I can answer that question.

All findings described in this paper could be seen in those 120 or larger number of specimen. I see them over and over again.

BY MS. BYARD:

Q. But you don't have -- you don't have this completed data set that you had on these 24 specimens on all 120?

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A. We'll deal in data set. It's not a data set, it's a descriptive study which is describe what findings we could find. There is no statistics in it, if you can see --

I mean, there is statistics of frequencies in this specific 24.

Q. Right.

A. But it's not a comparison between what happens in those who experience these type of complication and the other one.

I mean, as I said, if we take generally the purpose of this study, pathology of explanted transvaginal meshes so -- and it was specifically focused on POP devices.

If I take all of the POP devices I examined, there will be no -- all of these findings can be seen there. And all of them can be included, and if you're trying to ask me if I selected them specifically, no. I can expect these findings in any POP devices.

Q. Actually, what I'm trying to understand, Doctor, is whether the data that you had to complete this study. So, for instance, here you have descriptions of the fragment size. You have descriptions of the heavyweight versus

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lightweight mesh, how many samples of each were included in these 24. You have examples of what area focally of the mesh was filled with loose connective tissue. You have statistics on the number of specimens that showed neural ganglia involvement.

I'm just trying to understand if all of those same data points have been obtained and exist in the spreadsheet, or however you keep it, for the 120 specimens that are referenced in your report?

MR. ORENT: Objection.

THE WITNESS: This data is obtained for all specimens which are completed, which excision is completed with surgical pathology report.

As you saw, as I mentioned, the surgical pathology report includes all of this because I examine all specimens according to standardized protocol.

So all of the findings which are described are even more since then are recorded, assessed, either they're there or they're not there.

How many of those have been completed, likely close to 100, but I haven't updated it recently because of an avalanche of work recently.

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BY MS. BYARD:

Q. Here under "Results," you mention that:

"Available clinical records indicated mucosal exposure as a reason for excision in 67 percent of cases --" do you see that?

A. Yes.

Q. And:

"Pain in 56 percent of cases, and both, in 33 percent of cases."

A. Correct.

Q. You also say that the product -- these 24 specimens, include products from three different manufacturers; do you see that?

A. Yes, I do.

Q. Which were the three manufacturers?

A. The earliest I received was AMS, and then you, and then probably Ethicon.

Q. Okay. So the study includes Boston Scientific devices?

A. By the time of this study, likely.

Q. Is there something you can check to confirm that for me?

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A. Yes, I should be able to do that.
MS. BYARD: Okay. We need to go off the record to change the tape.
THE VIDEOGRAPHER: This marks the end of media number two in the deposition of Dr. Vladimir Iakovlev.
We are going off the record at 1:08 p.m.
-- OFF THE RECORD DISCUSSION --
THE VIDEOGRAPHER: Here begins media number three in the deposition of Dr. Vladimir Iakovlev.
We're back on the record at 1:09 p.m. Go ahead, Counsel.
MS. BYARD: Thank you.
BY MS. BYARD:
Q. What did you mean by -- excuse me if I said this -- actually, let me withdraw that.
Here, if we turn to "Disclosures", Doctor. This reads:
"Authors provided medical-legal consultations on the subject."
A. Yes.
Q. At the time you published this article, you were working as a paid expert for

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Plaintiffs, right?
MR. ORENT: Objection.
THE WITNESS: No, I was working as a pathologist at St. Michael's Hospital. But I provided consultations, and I was paid for time I spent for consultations.
BY MS. BYARD:
Q. At the time that you published this report, you were still acting as a retained expert for Plaintiffs, right?
MR. ORENT: Objection.
THE WITNESS: What do you mean "acting"? I mean, my main job is pathologist at St. Michael's Hospital and assistant professor at the University of Toronto. I do provide medical-legal consultations when asked.
BY MS. BYARD:
Q. Your relationship, your consulting relationship with Plaintiffs' counsel, hadn't ended by the time this report was published, right?
MR. ORENT: Objection.
THE WITNESS: That's correct.
BY MS. BYARD:
Q. It was ongoing?
MR. ORENT: Objection.

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THE WITNESS: That's correct.
BY MS. BYARD:
Q. You were a paid expert for the Plaintiffs in mesh litigation before you published this report, right?
A. Yes.
Q. And you continue to be one today?
A. Yes, I am.
Q. That relationship hasn't stopped since it began?
MR. ORENT: Objection.
THE WITNESS: No, but you made it sound as if it's my full-time job.
BY MS. BYARD:
Q. I didn't mean to imply that. What percentage of it is your income?
A. As I said, I mean, I haven't completed billing, and I haven't -- last year it was less than 10 percent.
Q. And this year do you have an estimate of what percentage litigation consulting work for Plaintiffs will make of your overall income?
A. Probably more than last year, likely more than 10 percent. But how much more, I

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don't know. Less than 50 percent, anywhere between 10 to 50 percent.
Q. Here, though, in your disclosure it doesn't say which side your consulting work was on, does it?
MR. ORENT: Objection.
THE WITNESS: No. But should I bias readers, or just tell them that I may be biased? Because if I start disclosing then, further details, I introduce extra bias.
BY MS. BYARD:
Q. Well, it could cause some authors to discredit your -- some readers to discredit your work, because they know that your work was for one side versus the other; is that what you're saying?
MR. ORENT: Objection.
THE WITNESS: It's up to readers to decide if there is a bias in the paper. I just provide them this information that I may have a bias. Which way and how -- I mean, I can be criticizing specific type of mesh and working for another manufacturer, who is trying to sell not polypropylene mesh. I mean, there might be multiple biases.
But it clearly states that I can be

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biased in this paper, and I disclose it.
BY MS. BYARD:
Q. It sounds like this is something you've thought about this before?
A. What do you mean?
Q. Did you make a conscious decision about whether or not to include that it was for one side versus the other that you were doing this consulting work?
MR. ORENT: Objection.
THE WITNESS: I always approach everything trying to be as neutral as possible, and give neutral information. I mean, it's always in my head.
BY MS. BYARD:
Q. So did you have a discussion with Dr. Carey and Dr. Steege about whether you should put which side your consulting work was on?
A. No, I don't remember if we discussed the specifics. I mean, usually, it's disclosed conflict of interest, and people describe them as the way they think is most appropriate. Sometimes journal has specific requirements, how you describe it.
Q. So, for instance, if a study -- a

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clinical study, let's say, was funded by Boston Scientific, it would indicate that it was funded by Boston Scientific, if the author was following, what you've described as the best practices, right?
MR. ORENT: Objection.
THE WITNESS: If a study is funded by a specific agency, there might be a specific question.
When you submit it, it might be just a drop-down menu. Was it funded by someone; by whom? Then you have to disclose it.
If it's a free text, what you disclose, you can say that funding came from this, this and that agency. And then readers can decide if it can have a bearing on the conclusions.
BY MS. BYARD:
Q. How common is it for you to see a disclosure that says, "this research was funded" without any indication as who the funding was from?
A. What do you mean "funded"? Usually when it's funded it says a grant or something else agency.
Q. The disclosure tells you who funded?
A. Yes. But this study wasn't funded.

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Q. Peers, just picking up this article, this article alone, wouldn't know that you have testified for plaintiffs against mesh manufacturers in seven depositions and at two trials, would they?
MR. ORENT: Now you're misrepresenting the timeline and facts of this case and being argumentative.
THE WITNESS: I just don't understand where you would see that somebody would list all the depositions and everything else in disclosure.
Disclosure, as I said, if it's funded, usually the funding agencies provide it.
If there are other conflicts of interest, they just provide it through best sort of neutral, or shortest way, or depending on the paper.
This paper wasn't funded by anyone. I received the specimens from different sources, and we analyzed it, and there was no additional work to what usually pathology laboratory does.
BY MS. BYARD:
Q. So the words "for plaintiffs" does not appear in this disclosure, right?
MR. ORENT: Objection.

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THE WITNESS: No. And, essentially, it was part of the purpose not to bias it in this way.
As I said, there might be multiple biases. Plaintiff, not plaintiff, the manufacturer can be presenting different type of biases.
Plaintiffs have claims that it caused damage. But at the same time, there might be another manufacturer which can introduce bias. As I said, there's two types of devices on the market and so forth. There might be multiple biases.
BY MS. BYARD:
Q. As a reader, someone could not tell which type of multiple biases that are possible could have influenced your writing on the subject?
MR. ORENT: Objection.
THE WITNESS: That's not the point. The point is that to disclose that there might be bias. And -- if you are funded by an agency, assuming. So, you assume that that agency has -- either doesn't or has some control of what is being published and what is not being published.
But it's not included in the statement; it just states what's the agencies. It's up to readers to think if it could have an affect on the

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researcher or couldn't.
So this is how it is done. It is disclosed to the most neutral way, and then it's up to readers to see if the paper, paper itself, contains any information that it could have been biased.
BY MS. BYARD:
Q. And part of how you evaluate that is by knowing who funded the study?
MR. ORENT: Objection.
THE WITNESS: No, no. Not exactly.
BY MS. BYARD:
Q. Part of the way that you do that is knowing who prior consulting work was for?
MR. ORENT: Objection.
THE WITNESS: I would say not who funded the study, but if the funding agency could have an effect or control on the researchers, that's the most important question.
I mean, most of the clinical studies or other are funded, because it's such an expensive -- but then it's up to readers to see if funding agency could control, could have an effect. It may be not direct.
I mean, like you focusing on

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manufacturers. But there are some non-for-profit organizations which are funding with grants and everything else, and there is a competition to get these grants and so forth. So you might be biased to produce better results in order to renew a grant and so forth.
So this is a different bias. It might be even stronger than just financial bias. It's the same financial bias, because you are acquiring grants from there. Again, it's up to the readers to decide if that specific funding agency could have an effect.
Medical-legal consultation means that somebody provided opinion and was paid. So this can create a bias, and it's up to readers, again, go and see if there is any indication that there was a bias. And I provided bias -- that, that possibility.
BY MS. BYARD:
Q. Let's see what we can agree on, because you've said a lot on this.
All I want to know is whether the word "for plaintiffs" appears in this sentence?
MR. ORENT: Objection. That's been asked and answered.

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THE WITNESS: Have you ever seen --
BY MS. BYARD:
Q. Does the word appear there, Doctor?
A. No, it's not --
MR. ORENT: Counsel, you're not entitled to badger the witness. He's answered your question four times. You're trying to clearly get your bullet point, you can read the article just as well as any of us.
The Rules of Civil Procedure do not permit badgering of the witness, so move on.
MS. BYARD: It's my deposition and I'm entitled to get answers to my questions.
BY MS. BYARD:
Q. My question is simply this, Doctor:
Under the disclosure, in your study with Dr. Carey and Dr. Steege, it says, "authors provided medical-legal consultations on this subject." It does not say "for plaintiffs," does it?
A. No, it does not --
MR. ORENT: Objection.
THE WITNESS: -- state. I could have been providing for both Plaintiffs and

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manufacturers.
BY MS. BYARD:
Q. As a reader, I would have no way of knowing which side your testimony had been paid for by reading your article?
MR. ORENT: Objection.
THE WITNESS: You shouldn't have to know. You should be able to go through the paper and try to find clues if there was a bias. Because that's the whole point of critical appraisal in the literature.
If somebody tells you from the beginning, that this study is biased because it was paid and so forth, would you read this article?
BY MS. BYARD:
Q. Is that part of the reason why you didn't disclose which side you were on?
A. No, I'm just saying that I never seen a single paper where the disclosure was formulated the way you're trying to introduce.
I have never seen when it states that somebody was consulted on side of plaintiff. Maybe they exist, but I've never seen it.
Q. Have you seen disclosures where it says, "doctor so and so provided consulting for

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such and such company"?
MR. ORENT: Objection.
THE WITNESS: Usually it's financial disclosure. "This funding was sponsored or funded in part by this manufacturer" or something like this.
I don't remember specifically wording like you've just said. Usually they describe funding agency or manufacturer in terms of funding source.
EXHIBIT NO. 1199: Abstract entitled, "Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh is Not Inert," by Dr. V. Iakovlev, Dr. G. Mekel and Dr. J. Blaivas
BY MS. BYARD:
Q. I'm handing you Exhibit 1199.
And this is another publication of yours from this year, right, Doctor?
A. That's correct.
Q. And this is an article that you published with doctor -- I'm sorry -- an abstract that you published with Dr. Mekel and Dr. Blaivas, right?

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A. That's correct.
Q. And Dr. Blaivas is a paid Plaintiffs' expert, too, right?
A. I know that he gave his opinion to some cases.
Q. For the Plaintiffs, correct?
A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of this.
Q. So of the cases that you're aware of, he testified for the Plaintiffs?
A. Yes.
Q. You write:
"Over the last decade polypropylene mesh slings have become the most commonly performed operation for stress incontinence."
Correct?
A. That's correct. Did I write -- where did I say -- (Witness reviews documents.)
In part. It could be part of my wording and part of other --
BY MS. BYARD:
Q. That's the language that appears

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here.
A. Coauthors. Yes, you read it correct.
Q. Here there is a discussion of, again, looking at specimens. This time of transvaginal slings; do you see that?
A. Yes, this was limited to slings.
Q. How many specimens were included in this write-up? I thought I saw 63 in Table 1.
A. Yes. So a total number was 63, 18 were retropubic and 45 were transobturator.
Q. Here, for the 63 studies, you used scar tissue from non-mesh excisions as a reference control?
A. Just general understanding, how it looks and what are the pathological findings, yes.
Q. There wasn't any sort of objective measuring of the number of nerves, or the number of blood vessels like we saw in your hernia mesh study with Dr. Bendavid, right?
A. No. In this case, scar tissue was used more for a reference for inflammation, for foreign body reaction and other mesh-related changes.
Q. I wanted to understand the

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sentence two, three lines in, under "Interpretation of Results" where you write:
"In contrast, mature scar tissue after non-mesh surgeries does not show inflammation."
Do you see that?
A. So can you point where you --
Q. Sure. Underneath "Interpretation of Results," the third sentence in.
MR. ORENT: Paragraph 2.
THE WITNESS: "In contrast, mature scar after non-mesh surgeries does not show inflammation." Yes, that's correct.
BY MS. BYARD:
Q. What does "mature scar tissue" mean?
A. Mature scar tissue. Scar tissue is mature.
Q. Is there a point in time when scar tissue shows evidence of inflammation?
A. When it's really early in its development. I mean, the first initial reaction to injury, the initiating event of scarring is associated first with the formation. First neutrophils come, and then macrophages and then --

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Q. And we don't really need to go into all that, because I do understand that from your deposition before. I appreciate that, thank you, Doctor.

What I'm trying to understand is when in time you will stop seeing inflammation in the development of scar tissue?

A. Sometime after few weeks of healing.

Q. How long will it take for nerves to begin to ingrow in scar tissue?

A. Also happens within first few weeks of healing.

Q. First few weeks -- are we talking one to four weeks, or are we talking one to six weeks? What's the window that's accepted?

A. It's very variable. It depends on individuals, conditions, repetitive injury. And all this process are continuing from about day three to anywhere six, eight weeks, maybe longer. If there is continuous injury, it may repeat itself during years.

Q. So if a patient, for instance, complained of immediate postoperative pain, would it be fair to say that nerve ingrowth in mesh

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structures could not be the source of that pain, because nerves could not yet appear growing within the mesh structure?

A. Yes, that's correct.

Q. Okay. And here you talk about potential sources of pain, you write:

"Within these mini compartments, the innervated tissue is exposed to potential sources of pain such as compression, stretching, inflammation, ischemia, etcetera."

A. That's correct.

Q. But you would agree these potential sources of pain are also present in scar tissue where there is compression, stretching of the scar tissue, inflammation in the scar tissue, ischemia, etcetera, wouldn't you?

A. No.

MR. ORENT: Objection.

THE WITNESS: No, I wouldn't agree. There is no inflammation, there is no edema, scar tissue doesn't show conditional edema. Scar is pliable, it can change over time. So if there is shrinking, it will slowly change because it's native tissue.

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There are multiple differences between a scar without mesh and a scar with mesh.

BY MS. BYARD:

Q. In this discussion where you say, "scar tissue from non-mesh excisions were used as reference controls," are you referring to the scar tissue that you used from the abdominal wall in the Dr. Bendavid study, or were you specifically referencing scar tissue from vaginal mesh excisions?

A. In this case, specifically for vaginal mesh. I mean, they were not grouped together, but either with the specimens, sometimes I received just scar tissue without mesh outside. Sometimes it's just a scar excision and surgeon identifies it as a scar excision. Or sometimes we receive it in the course of some surgeries in St. Michael's Hospital, so I visually know what it looks like.

Q. And then you go on to write that:

"Surprisingly, easily visible in the microscope, it has been overlooked for 50 years."

And there you're describing what you've coined as a term, "degradation bark"; right?

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A. Yes, that's correct. The degradation layer was not described as it appears in the light microscope.

Q. And that's what I was getting at earlier. On the one hand you told me degradation of polypropylene has been described since the 1970s. And then here, in this abstract that you publish with Dr. Blaivas, you say it's been overlooked for 50 years? I was trying to reconcile that.

A. Well, it's clear. This states about microscopic appearance and the cross-sections in a light microscope, and I'm talking about detection of degradation by other means, either scanning electron microscopy or mechanical testing. So this is specifically for microscopic appearance and light microscope.

Q. So if you were going to complete the following sentence: "I was the first pathologist to observe..." what?

MR. ORENT: Objection to form.

THE WITNESS: I don't know if I was first one.

BY MS. BYARD:

Q. You were the first one to report

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findings on degradation of -- degradation bark under polarized light in microscopic observation?
MR. ORENT: Objection.
THE WITNESS: I'm the first one who is describing light microscopy features of polypropylene degradation. So that would be a full definition. To my knowledge, I am the first one.
BY MS. BYARD:
Q. To your knowledge, nobody else has done it besides you up until this point?
A. Nobody published.
Q. You continue:
"From mesh exposure an important finding was that sling edges rotated or curled towards the surface at the exposure sites."
Tell me what you meant by that.
THE WITNESS: Sometimes when a reason for excision is mesh exposure, the mesh, if you can see the mesh is rotated -- if this is the mucosal surface, I can see it's rotated. I can see the curl. If it is a big enough piece and well oriented then I can see it.
BY MS. BYARD:
Q. Based on your observations to

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date, are you able to say whether the exposure of the mesh causes the curling or whether the curling causes the exposure?
A. Sometimes it's not curled, but it's still exposed. So I make a conclusion, curling which makes it exposed.
Q. Sometimes it's exposed but not curling, though, right?
A. Yes.
Q. Okay. So something other than the curling causes the exposure in those instances?
A. There might be different mechanisms, but one of the mechanisms is curling.
Q. Okay.
A. Most of the curled part is inside the exposure site. It's only the tip which is exposed.
Q. And you haven't done a statistical analysis in order to say whether or not this edge curling phenomena occurs with a statistically -- at a statistically significant rate with exposures to conclude there's a causal relationship, right?
MR. ORENT: Objection.
THE WITNESS: I don't understand what would you compare with -- I mean, what -- I mean --

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BY MS. BYARD:
Q. So you could design an experiment where you looked at incidences of exposure, and whether or not there was curling, and also a control sample where there's curling but not exposure, right?
A. I can tell you for sure, if I see the edge rotated towards, the mesh was curled 100 percent.
Some cases I see curling completely outside of the exposure -- if there's no exposure surgically described. So, based on these two observations, I can state if curling occurs close to the surface, the edge is prone to be exposed.
Q. You can't say that exposures occur at a statistically significant rate with curled mesh edges?
A. But --
Q. Over non-curled mesh edges?
A. What do you compare it with? You have to -- clinical experiment would be, curled meshes are placed right under the mucosa, and then the rate of exposure is measured. Can you do that? You can't.
Every time I see it's curled at the

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mucosa, it's exposed; 100 percent, as I said. If it's not at the mucosa, it cannot be exposed because it's too far. You cannot design experiment in this retrospective way.
Q. Well, there isn't an edge if it's not exposed though?
A. No, I don't -- so if you want to assess the rate of exposure, which would occur due to curling, you would have to place flat meshes under the surface and then curled meshes under the surface, observe them for five, six years, and then calculate the rate. That would be start answering your question.
Right now what I see, if it's curled and it's at mucosa, it's 100 percent exposed. But as I said, sometimes it's flat and it's still exposed. Or, in orientation I cannot assess if it's curled, not curled. It's just poor orientations.
Q. You conclude with a message:
"Polypropylene degradation needs to be studied further for its role in inflammation, mesh hardening and late deformation, as well as for the properties of chemical

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degradation products."
Did I read that correctly?
A. That is correct.
Q. And here again, what this conclusion reinforces, is that there's a need for a further study to understand the details of the mechanisms of actions of the relationships between degradation and inflammation, as well as mesh hardening, and whether any chemical degradation products are produced or what they are, right?
MR. ORENT: Objection.
THE WITNESS: That's correct. Because what we know? We know that some patients present with complaints six or eight years after the insertion.
So the only thing which changes over time is the degree of degradation. So degradation layer or bark is getting thicker, so it's inflamed and so forth.
So from what we know now, the only late factor which happens around the mesh or to the mesh is degradation. So those changes which occur later on, will have more -- larger component of degradation within the mechanisms of this.
But how exactly it occurs, then again,

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it needs to be studied. Or, if I observe a bark or degradation layer, I can see the cracks in it. I know that they're internal forces which shrink it. But how much of that, how all these forces work, I mean, it all needs to be studied.
BY MS. BYARD:
Q. You also write here one sentence before this:
"The compartmentalizing nature of the meshes and nerve ingrowth might create a background for the pain mechanisms."
Do you see that? It's just one sentence before the one we just read.
A. Can you point on your copy?
Q. Yes, here.
A. Yes, that's correct.
Q. Again, you've used this word "may"?
A. Again, because all these --
Q. That's my only question. That's the word that you've used, right?
A. Well, it's written.
Q. And there's no disclosure of any conflicts of interest related to medical-legal

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consulting in Exhibit 1199, right?
A. Well, this is --
MR. ORENT: Objection.
THE WITNESS: -- clearly disclosed.
BY MS. BYARD:
Q. Where?
A. "Some external consultations sent for litigation purposes" -- see, again, this was a very structured way of submitting abstract. I didn't have much flexibility to put in. I had a drop-down menu for funding only.
See if it's -- see, funding, subject, ethics committee and everything else, I could enter only specific amount of information in the drop-down menu. So I tried my best to disclose as much as I can.
Q. So your testimony is that for 1198 and 1199, there was a free text field you could type in?
MR. ORENT: Objection.
THE WITNESS: To a certain degree -- I don't remember exactly now but I mean it was -- which one?
BY MS. BYARD:
Q. The one we looked at before where

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you published with Dr. Carey?
A. This one was free text, just submitted paper. It was just, um, paragraph disclosures, this one was more restricted.
Q. And so -- but you typed in the words, "Some specimens were received as external consultations sent for litigation purposes."
A. That's correct. Yes, I did it.
Q. And again, the word "for Plaintiffs" does not appear here, does it?
A. No. But, as I said, we discussed it before.
MS. BYARD: We need to take a break now for everyone.
THE WITNESS: So it's 20 to 2:00. Do we take a break and then come back? I can still go on for another hour or so.
MS. BYARD: Do you mind if we discuss this off the record?
MR. ORENT: Yes, sure.
THE VIDEOGRAPHER: Going off the record at 1:40 p.m.
-- RECESS AT 1:40 p.m.
-- UPON RESUMING AT 2:16 --
THE VIDEOGRAPHER: We're back on the

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record at 2:16 p.m.
BY MS. BYARD:
Q. Doctor, I'm handing you Exhibit 1200. I'll ask if you recognize that?
A. Yes, I do.
Q. This was an abstract that you published this year with the -- let me start over. This was an abstract that was published this year?
A. Yes, that's correct.
Q. The title is, "Explanted Surgical Meshes: What Pathologists and Industry Failed to Do for Over 50 Years"; is that right?
A. For 50 years.
Q. Thank you. Under "Objective" you write, three sentences in:
"Estimated millions of devices have been excised over the years, however, the study material remain largely ignored and the mechanisms of complications are still poorly understood".
A. That's correct.
Q. Under "method" you write:
"130 meshes excised from different anatomical sites were

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studied in search of features explaining the complications."
Did I read that correctly?
THE WITNESS: That's correct.
BY MS. BYARD:
Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh?
A. Yes. At that time, yes.
Q. Did they include any other anatomical sites or types of polypropylene mesh?
A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or...
Q. I was just thinking of the indication.
A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations.
Q. And your report in the litigation which has been marked as Exhibit 1196, you wrote that the explanted transvaginal mesh specimens that you've examined include slings and POP devices, heavy and lightweight netted polypropylene and Gore-Tex and combined designs.

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My question for you is whether this 130 meshes includes Gore-Tex and combined designs in addition to polypropylene mesh?
A. No. This would just be POP and knitted polypropylene meshes.
Q. And then you describe here some findings that we've already discussed in relationship to your other article with Dr. Carey, correct?
A. That's correct.
Q. Are there any findings reported here that are different, or in addition to the findings reported in the full length article that you authored with Dr. Carey and Dr. Steege?
A. Um, this was a smaller abstract which, as you can see, combine transvaginal meshes, slings and POP devices and hernia meshes. So this is more of a descriptive study of all meshes, irrespective of their anatomical location. Where other papers were concentrated on specific type of transvaginal locations, whether slings or POP devices.
Q. And so it wouldn't be true to say that the 120 specimens that you described in your litigation report are all included in this abstract, correct?

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A. You see the abstract was written earlier, a few months earlier so...
Q. The reason why we get to 130 specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?
A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool.
Q. Can you tell me how many of these 130 specimens were transvaginal mesh?
A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this --
Q. Okay.
A. -- roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes.
Q. Okay. So including sources of specimens from -- provided to you from Plaintiffs' counsel in the mesh litigation?
MR. ORENT: Objection.
BY MS. BYARD:
Q. Correct?

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A. There was 97, yes.
Q. You conclude that:
"General lack of interest created a paradoxical gap of knowledge in the presence of abundant study material and readily available tools."
Right.
A. That's correct.
Q. You continue:
"The newly described findings need to be studied in correlation with clinical symptoms to guide future developments."
Correct?
THE WITNESS: That's correct.
BY MS. BYARD:
Q. This study doesn't describe any correlation of your histological findings with clinical symptoms, does it?
A. No, not directly.
Q. There is no conflict of interest disclosure in Exhibit 1200, right?
A. It was provided later in the presentation, I believe. It's just the way it was

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published.
I think I gave disclosures during submission. But the way they publish it, there's no disclosure. I can see there's no other disclosures for any other abstracts.
Q. There's not a disclosure that appears here in Exhibit 1200, is there?
A. On the paper, no.
MR. ORENT: Objection.
THE WITNESS: But it doesn't mean that it was not provided, or was not disclosed elsewhere assuming for presentation.
If it's a presentation, I give slide with some disclosure, which is usually first slide before the presentation.
BY MS. BYARD:
Q. Okay. If you're able to find the disclosure form that you think you might have completed for this, would you provide it to counsel for me?
A. I could not have it, because it was electronic submission.
Q. Okay.
EXHIBIT NO. 1201: Abstract entitled, "In-vivo Degradation of Surgical

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Polypropylene Meshes: A Finding Overlooked for Decades," by Dr. V. Iakovlev, Dr. S. Guelcher, Dr. R. Bendavid.
BY MS. BYARD:
Q. Exhibit 1201 will be passed to you here momentarily.
MR. ORENT: This is 1201 you said?
MS. BYARD: Correct.
BY MS. BYARD:
Q. The title of 1201 -- well, first I should ask, this is familiar to you, right?
A. Yes. That's the same conference, the same submission process. The same journal, the same issue.
Q. The title of this abstract is: "In vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades."
A. That's correct.
Q. And this is published with Dr. Scott Guelcher and Dr. Bendavid, right?
MR. ORENT: Guelcher.
THE WITNESS: Guelcher.
BY MS. BYARD:
Q. Thank you. And Dr. Guelcher is a paid Plaintiffs' expert like you, correct?

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MR. ORENT: Objection.
THE WITNESS: Yes. He served as expert witness.
BY MS. BYARD:
Q. On the Plaintiffs' side, as far as you know, right?
A. From those cases we've been involved together, yes, he was on Plaintiffs' side. Could have been on manufacturer side for something else.
Q. But as far as you know, it's been on the Plaintiffs' side, right?
MR. ORENT: Objection.
THE WITNESS: I don't make the distinction. Because as I said, I mean, this is up to me to decide, or any other reader if there is a bias on which side and how it is presented.
BY MS. BYARD:
Q. My only question is, as far as you know, he served as a testifying expert for Plaintiffs against mesh manufacturers, correct?
A. That's correct.
Q. Under "Objectives", you write:
"Surgical polypropylene meshes introduced over 50 years ago are

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excised in up to 10 percent for complications."
Did I read that correctly?
A. Yes.
Q. Is this a statistic for hernia mesh or for transvaginal mesh?
A. This is difficult now to remember. Because it was based on all of those. So "up to" means the highest number I could see in sufficiently reliable source.
Q. Sometimes the rate is lower than that in the reported literature, true?
A. It's a range. I mean, if you take small sample size, one single mesh which has not been excised, you don't have any rate. If a sample size goes larger, then you get more or less representative sample of the whole population.
Q. For this statement, were you including literature on rates of removal from both hernia repair and transvaginal mesh repairs?
A. It was pertinent to both. So I don't remember exactly if 10 percent was for hernia or transvaginal. I suspect it could have been for transvaginal from what I remember.
Q. You write:

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"We studied 103 explanted meshes and different designs, manufacturers and anatomical sites using conventional and transmission electron microscopy."
Correct?
A. That's correct.
Q. Why are we at 103 here, compared to the sample size of 120 we saw in Exhibit 1200?
A. Multiple reasons. It could be different point in time when this abstract was written. Something else, like not completed study at that time, because I would need polarize or measure the degradation thickness; so I don't know. But at that time when the abstract was written, total number was 103.
Q. You conclude this abstract by writing:
"The discovery --" and you're referring to the discovery of degradation under microscopy "-- opens the door to study the role of degradation in the development of complications."
Right?

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A. Yes.
Q. That study has not yet been completed, true?
A. What exactly? Which study?
Q. The study of the role of degradation in the development of complications?
A. It doesn't state it there as a study.
Q. You write:
"The discovery opens the door to study the role of degradation in the development of complications".
A. Yes. But it doesn't state that we have a study ongoing to do that. "Study" is used as a verb here not as a noun.
Q. You haven't yet published anything on the role of degradation and the development of complications, right?
A. On exact mechanisms? No.
Q. There is no conflict of interest disclosure in Exhibit 1201 for you, is there?
MR. ORENT: Objection. Asked and answered.
THE WITNESS: The same thing. During submission there was an option, if there was an

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option, submitted all information I could during presentations. If it's PowerPoint presentation, the first slide which appears after the title slide is disclosure of conflict.
BY MS. BYARD:
Q. A conflict of interest disclosure does not appear in Exhibit 1201, does it?
MR. ORENT: Objection.
THE WITNESS: It's up to a journal.
BY MS. BYARD:
Q. Is there a conflict of interest disclosure that appears in Exhibit 1201, sir?
MR. ORENT: Objection.
THE WITNESS: I don't see it.
Maybe it was somewhere at the end of the journal issue, I don't know. I mean, this is just a page from the issue. Maybe they had conflict of interest gathered at the end.
BY MS. BYARD:
Q. I'd like to turn back to your report, which is Exhibit 1196.
Are you on the "Opinion" section with me, sir?
A. Which page number?
Q. Five, please. You write that:

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"Explanted mesh specimens show non-specific reaction of the body to a foreign object, as well as findings specific for a mesh type or an anatomical location."

Is that right?

A. That's correct.

Q. You continue:

"Findings for abdominal mesh explants differ from findings for vaginal mesh implants."

A. That's correct.

Q. How so?

A. I've explained some of the differences earlier. Hernia meshes are placed in parallel to anatomical planes. There are separated, well defined planes between fascia, adipose tissue, muscle and transvaginal allocations. There is no fascia, really, there's no anatomical plane. The tissue gradually transitions into -- one to another.

Another difference is that functionally, abdominal wall is just holding pressure of -- abdominal pressure. While vaginal tissue has completely different purpose. There is more

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mobility, there is stress of bladder expansion, bowel movement, then stress of intercourse.

Muscles within the bladder wall, muscles within the vaginal wall which contract, type of innervation is completely different.

Where in the abdominal wall, it mainly serves as a passage of nerves parallel to abdominal wall, where the vagina is practically the target of innervation, because the endings are there, and the nerves are in different orientation.

And I can continue on and on, I mean it's -- abdominal wall is a completely sealed environment, there's no contamination. Vaginal environment is contaminated. Do you want me to continue?

Q. Are those the main differences that you're noting?

A. I mean --

Q. Those are the ones that are important to your opinions here?

A. I can continue more with the differences.

Q. Are they relevant to your opinions in this report, the other differences besides those that you've mentioned?

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A. Yes. They are important to understand. I mean, everything is important to my opinion, because I wouldn't be providing this opinion if I didn't go to medical school. So you have to go back to 1986.

Q. I don't think we have time for that, unfortunately.

Under paragraph 2 of your opinions, there's a sentence that reads:

"This reaction --" and you're talking about the foreign body reaction "-- persists until the inciting agent is either removed, in parenthesis, [expelled or reabsorbed]."

Are you with me?

A. "Resorbed".

Q. Resorbed. Thank you.

Does there come a point in time, in the tissue response to mesh, where the inflammatory response reaches a chronic or steady state?

A. Foreign body reaction is a chronic inflammatory reaction.

When it starts, it may start acutely but on its own it's a chronic response. Not may start; it starts acutely after the placement of

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foreign body, and then continues on as a chronic response.

Q. Does the foreign body response drop off over time?

A. Not in what I see. In relation to polypropylene, I see even -- I think my oldest specimen was 12 years after insertion, and I still see inflammatory -- chronic body -- chronic foreign body type reaction.

So in relation to polypropylene, it's a variable. But I've never seen it went away completely.

Q. Does the foreign body reaction drop off after this acute phase that you've described? And I don't mean completely, but just decrease?

A. That was one of the questions. And I would expect that it would decrease, but so far have not been able to show it. Every time I'm checking, every time data builds up and then I check if there is correlation between foreign body reaction, what degree, and I'm just -- it doesn't correlate yet.

Maybe I need to go to a thousand cases and then I see some weak correlation. What seems

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to be a case that it's variable between individuals, or maybe it's variable within the same individual, so it fluctuates with time. But again, that's why we need to study all this.

Q. So those conclusions haven't been established yet, based on your observations to date?

MR. ORENT: Objection.

THE WITNESS: What exactly defines the degree of foreign body reaction? No, the degree is not.

I mean, we know --

BY MS. BYARD:

Q. The degree -- and I guess what I'm focusing on is, it's activity over time?

A. Yes. This is not completely understood. What we know, it is present and it is always present.

Q. Okay.

A. In all specimens.

Q. You write here in your third paragraph that:

"A mesh is a large foreign body in comparison to regular surgical sutures." Right?

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A. That's correct.

Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs?

A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be.

Q. Have you ever seen the performance of an abdominal paravaginal repair?

A. I've seen some surgeries, I assisted to some surgeries. And definitely there are not that many sutures, in any surgery, I would say.

In any type of surgery, you probably now ask me for specific surgical techniques. No surgeon will insert that many sutures, that much of foreign body in the -- during the surgery. There's no need for that.

Q. My question to you, sir, was whether you've ever seen an abdominal paravaginal repair performed; and I think your testimony is that you can't say for certain you have seen abdominal pelvic surgeries performed?

A. I have seen some pelvic abdominal surgeries, but I don't know exactly what type of

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that was. I mean, I just don't remember now.

Q. Okay. And that's fine. And I think your testimony in response to my question about how many sutures are placed, for example, during abdominal paravaginal repair, is that you don't know for certain that the amount of materials are less than with the surgical mesh; is that fair?

A. Significantly less, that is fair.

Q. You write in paragraph 4 of your opinions, and I'm just reading part of the sentence that I want to ask you about is that:

"The filaments --" here you're referring to vaginal mesh "-- are always surrounded by fibrous scar."

Do you see that?

A. Yes.

Q. Is it true that you see tissue changes to mesh adjacent to the mesh, but at some point you see a resumption in normal tissue response?

A. What do you mean, "resumption of normal tissue response?"

Q. So you see a foreign body reaction and chronic inflammatory state in the tissue immediately adjacent to the mesh, correct?

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A. That's correct.

Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct?

A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal.

Q. Okay.

A. So --

Q. So then maybe if we can --

THE WITNESS: -- there is an edge ----

MR. ORENT: Hold on. Slow down and let him answer.

THE WITNESS: There is an edge of changes of scarring, and then there is normal tissue. So if you use word "response," it means abnormal already.

BY MS. BYARD:

Q. Okay, thank you for that correction.

There's an edge that you see away from the mesh, where there's a resumption in normal tissue?

A. Yeah. Interface between scar and normal tissue.

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Q. Have you measured to find a range at which the average return to normal tissue is from the mesh?
A. I don't think you're using words "return" is not --
Q. Okay.
A. It's not applicable. You don't know if it was scar and then return -- actually, it's impossible.
Q. Okay. So is there, I guess -- and help me with how to phrase it. But is there a distance -- have you measured -- let's start over.
Have you measured how far away from the mesh the tissue ordinarily appears normal?
A. Yes. I didn't perform statistical analysis or study, but I measured approximately what's the distance of changes.
Q. And what is that distance on average?
A. It's within one to two millimeters, not greater than two, at least from most of the cases I see.
Q. So in most instances, when looking at a transvaginal mesh and tissue specimen, you will see normal tissue one to two millimeters from

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the mesh?
A. Yeah. From the most, outermost point of mesh filament. Usually it's within one to two -- or I would say, to be safe, one to three millimeters. I don't see it exceeding three millimeters, unless there is something else, like an abscess.
If there's an abscess, then there is much more scarring in the area. Or, if there is erosion, there's inflammation, there is much more damage to the tissue, then it expands.
But if we go into deep environment and changes which can be only attributed to mesh, then it's within three millimeters beyond the mesh.
But, if the mesh is curled, or folded like POP, the distance between two mesh planes in the fold can be much greater, five, six millimeters, and this will all be filled by scar. I'm talking about extent towards normal tissue.
Q. That's what I was asking.
A. Externally, yes.
Q. Okay. Good.
MS. BYARD: Doctor, I want to keep you on schedule, so I know we need to break for an appointment. Let's do that now.

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THE WITNESS: Thank you.
THE VIDEOGRAPHER: Off the record at 2:44 p.m.
-- RECESS AT 2:44 --
-- UPON RESUMING AT 4:35 --
THE VIDEOGRAPHER: We're back on the record at 4:37 p.m.
BY MS. BYARD:
Q. Doctor, attached to your report are a number of figures numbered 1 through 20, correct?
A. Figure sets, I believe, sometimes they are gathered in sets.
Q. Sitting here today, is it true that you are not able to tell me what clinical complications or symptoms led to each of these patients whose specimens are depicted in Figures 1 through 20? Wait, let me start over, I don't think I finished that right. Strike that.
Now, is it true that sitting here today, you're not able to tell me that clinical symptoms leading to these excision surgeries of each of the patients whose specimens are depicted in Figures 1 through 20?
A. You mean, do I remember the

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history for a specific photograph and --
Q. (Nods).
A. I don't. Is it what you meant?
Q. Yes, that was what I meant. Thank you.
A. I don't remember histories, I mean, they are all collected from Boston Scientific -- or most of them. If it's not, they are specified to be a known Boston Scientific.
Q. Okay. And so similarly, you aren't able to tell me that for the figures numbered 1 through 20, when any symptoms began, that led to the excisions resulting in the specimens whose -- that are depicted in Figures 1 through 20, right?
MR. ORENT: Objection.
THE WITNESS: When specific symptoms began?
BY MS. BYARD:
Q. (Nods.)
A. No, I cannot.
Q. Okay. Thank you, Doctor.
Returning to your report and paragraph 5; do you have that there in front of you?

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A. Yes.
Q. I just want to look at one sentence there at the end, where you write that:
""Mature scar tissue after non-mesh surgeries --"the sentence continues "-- can remodel with time."
Can you see that?
A. Yes, I do.
Q. Is it your opinion that scar tissue from mesh surgeries can't remodel with time?
A. Cannot or can?
Q. Cannot.
A. It can. It can remodel, but the mesh cannot remodel.
Q. So the scar tissue -- I'm sorry.
A. So there will always be scar around the mesh. If mesh travels, migrates, the scar will remodel.
So does that answer your question?
Q. Yes, it does.
So you would agree with me that scar tissue surrounding mesh can remodel over time?
A. Yes, it can.
Q. Okay. The sentence continues that:
"Mature scar tissue from

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non-mesh surgeries does not exhibit the same long-term reactions or clinical complications".
Do you see that?
A. That's correct.
Q. I just want to focus on the term "clinical complications" with you, okay?
Would you agree with me that there is no peer-reviewed published literature concluding that non-mesh surgical procedures are free of long-term clinical complications?
MR. ORENT: Can you read that back? I'm sorry.
THE WITNESS: I'm confused as well, yeah.
REPORTER'S NOTE: Whereupon the question was read back as follows:
"Would you agree with me that there is no peer-reviewed published literature concluding that non-mesh surgical procedures are free of long-term clinical complications?"
THE WITNESS: You can state it for any type of -- well, not --
MR. ORENT: I object to the form. Go

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ahead.
THE WITNESS: We have to kind of separate it, other clinical publications saying that mesh -- non-mesh surgeries are free of complications?
No. Because any surgery has a form of complication -- early complications, or later complications. I mean, it depends what surgery. I mean, then again, it's so broad and kind of worded in --
BY MS. BYARD:
Q. Okay, sure. And I just wanted to see if we could agree that non-mesh surgeries can also result in long-term clinical complications?
MR. ORENT: Objection.
THE WITNESS: Which -- I mean, any surgery will have specific complications. Early or later, we have to take specific surgery and then compare. Non-mesh surgery will not have long-term complications of meshes; that's clear.
If there is no mesh, there will not be complications related to the mesh. If there is mesh, there can be complications related to the mesh.

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BY MS. BYARD:
Q. So you can't cite for me, can you, what the rate of pain with a non-mesh perineorrhaphy is compared to a posterior repair with mesh; can you?
MR. ORENT: Objection. Outside the scope.
THE WITNESS: I'm not a clinician, so you have to ask other expert this question.
BY MS. BYARD:
Q. Okay, thank you.
Your next paragraph, paragraph 6, deals with your opinions related to degradation, right?
A. That's correct. Let me see.
(Witness reviews document).
Yes, that's correct.
Q. As I understand it, there are three principle findings from which you conclude that polypropylene mesh degrades in vivo, all right?
First you opine that the ability of the non -- I'm sorry, let me start over.
First, you describe that the ability of the degradation bark to trap histological dyes, evidences degradation in vivo, right?

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A. No, this is not correct. You're mixing up things. So let's split it.

If you want me to explain, I will explain. If you want me to answer your question, I will; what do you want?

Q. Okay. Well, you have three -- you have three basic findings.

A. No, no, not three. There are way more than three, but...

MR. ORENT: Just let her --

THE WITNESS: Okay.

BY MS. BYARD:

Q. Is it your opinion that polypropylene mesh degrades in vivo, in part because the degraded bark is able to trap histological dyes?

A. No, this is not correct.

Q. Explain it to me then.

A. So let's dissect it.

So first, what findings in the light microscope and electron transmission microscope through cross-sections prove that the layer I observe is polypropylene?

So the first finding, light microscopy, it polarizes. So it behaves as polypropylene --

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non-degraded polypropylene in polarized light. So this is first finding.

Second finding is that those mesh filaments where there are blue granules included, I observed them in this stainable layer. So this is another proof that it's coming from polypropylene.

Then with other stains, as for one cause of stain, because the stainable layer is brittle, it cracks. So the first question for pathologists would be, can it be calcified material? Which is very common to have calcified material in human body, especially with long-term chronic processes. So I did Von Kossa stain, calcium stain, it's not -- it's not staining for calcium.

The next set of stains was to stain for proteins, because if it's a protein, it mixes, it's a hydrophilic mix of some sort, to mix with proteins. So I stained it for several ubiquitous -- "ubiquitous" means present in many body fluids, immunoglobins, and it doesn't stain the layer. It's deposited right next to it, it goes into crevices, it follows the surface, but it doesn't mix. Again, this shows that the material is hydrophobic, and doesn't mix again; proof is

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that it's polypropylene. So these would be findings in light microscope. And if we go to transmission electron microscopy, I can see transition. I see non-degraded, sort of finely granule, almost smooth, no granulation, sort of granularity. And then there's a smooth transition into smaller cracks, fine lattice of cracks, and then it expands, and expands, and expands in larger crevices towards the surface.

So there's a range of degradation from a core to the surface. So this findings would confirm that this is -- this stainable layer is in fact polypropylene.

Q. Okay. So then what was wrong with my question --

MR. ORENT: Wait, hold on. He's not done.

THE WITNESS: Then there's a next set of findings, which is proving that it is altered or degraded polypropylene.

All right. First, we concluded that it is polypropylene. And the second set of findings proving that it's altered polypropylene.

Obviously, first thing which is visible in light microscopy is it observes dye.

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Non-degraded polypropylene is completely clear, it's solid, it doesn't have pores to trap dyes.

The degraded polypropylene absorbs dyes. And, if I do staining with two stains, one is with small molecular size of the dye, and one is larger molecular size of the dye. The smaller molecule -- the dye with smaller molecule size will retain in smaller cracks, really fine sort of microcracks. And then larger molecules would stay in the larger.

So, therefore, I had this trichrome stain layer of red, which indicates smaller porosity we see in the degraded material, and then a layer of green color, which highlights a larger porosity material. So this is degraded in light microscopy.

Cracking, that's another feature. Peeling off. So what happens, there is internal force -- it's like drying, it's like drying on lips or like rust on the surface of the metal. Because it shrinks somewhat, and then the internal force pulls it, there's a crack, but it pulls and sloughs off of non-degraded surface, and then it starts peeling.

So that's another feature showing that

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it's degrading, it's changing properties, physical properties and it's non-degraded material.

BY MS. BYARD:

Q. Okay.

A. And then there is a third set of findings, which proves that it happens in vivo. So "in vivo" means that it happens before it is --

Q. Explanted?

A. Piece of mesh is excised. So one of the findings is that some surgeries are done with electric cautery devices. So the edges of the specimen are burned, and it melts polypropylene. So this sides, I can see that the degraded material melted, and non-degraded material melted. And then they melt together and form one pool, and they merge together and crystalize together.

So this also shows that it is polypropylene, because in melted state, they're compatible. So they can recrystallize on their own.

But, it also indicates that the tool was touching it when it was already present. So it means that it was forming in vivo, before it was burned.

Another feature shows that it was in vivo, is when I measure degradation layer and

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correlated it with time, it was gradually growing over the years. So the first time when you can see it with light microscope, is probably about a year or two in vivo. And then there is a rapid growth which later on plateaus and goes really slow, which is biological response. I mean, it grows to a specific thickness, and then the rate of growth slows down. So this also proves that it forms in vivo.

Another thing I said, I put new meshes in formalin, and kept them in formalin up to four months, and then kept them -- and put them for processing and examined them. There's no degradation bark after four months. So, expose it to formalin up to four months, it doesn't form degradation. Again, if degradation is present and formalin doesn't cause it, it was present before surgery.

And then for transmission electron microscopy, the fact that inflammatory cells could migrate partially in the cracks, into crevices and expand, that's what they normally do, inflammatory cells go through very tight spots to migrate through the vessel walls. They try to do the same thing into the cracks of degraded material, but

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because it's dead then, they get stuck. So this is another process. Degraded material was present in vivo, while the inflammatory cells were mobile, so they could do that. So that's kind of overview.

Q. And maybe we're talking past each other. What I was focusing on was paragraph 6. And there you list its ability to trap histological dyes, right?

A. That's proof that it's altered.

Q. There you also list that it retains inclusions of blue granules?

A. That's proof that it was protein, that it's originating from original protein. Not protein, I'm sorry. Polypropylene. That it originates from polypropylene, which was manufactured with inclusion of blue granules.

Q. And then you list optical properties in polarized light, right?

A. Yes. Which are very different from anything else in the body, and this shows as well that it's polypropylene.

Q. Okay. So those were the three buckets I was talking about that were listed there in paragraph 6.

A. Yup. But then there is a

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description in the pictures with figure captions further going into the details.

Q. Okay. I understand that.

Have you just described for me all of the findings that you've made that lead you to conclude that polypropylene degrades in vivo?

A. I think most.

Q. I think so.

Can you identify for me, any peer-reviewed published literature, besides your own that we've looked at, that describe these three findings that are set forth in paragraph 6?

A. Okay. So you have to remind me which three findings; the blue granules?

Q. Blue granules, ability to track histological dyes, and optical properties in polarized light?

A. Blue granules, no. Polarized light has been used to identify foreign materials for decades.

Q. Okay. But not degradation?

A. Including degradation.

Q. Of polypropylene?

A. Not poly -- well, polypropylene is, no; because sutures were around. So what

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pathologists do, they see something, it's clear, it's not sure if it's foreign or a native tissue, polarize and see what's the state of it.

Specifically for degradation bark, the way I describe it, no. But, I mean, generally, pathologists identify foreign bodies, including polypropylene sutures, and they assess the state they are in.

Q. My question is more narrow than what you're responding to, okay?

My question is simply whether there is peer-reviewed published literature besides your own that we've looked at, that describes finding of degradation of polypropylene with polarized light?

MR. ORENT: Objection. Misstates the opinions of Dr. Iakovlev.

THE WITNESS: As I said, the state of polypropylene sutures and the examination in polarized light has been described before. Nobody coined it as I did as a bark, and went into these details, that's true.

But, was it used to see if polypropylene is there and if it's in degraded state or -- yes.

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BY MS. BYARD:

Q. Can you point me to an article that talks about identifying degradation of polypropylene sutures through the use of polarized light?

A. I'd have to search for it, but as I said, I mean, generally the tool is there and for diagnostic surgical pathologists they see foreign material, they have to assess what state it is in.

Q. Can you name an article for me, Doctor?

A. I cannot do it now, but I would have to search for that, but...

Q. Okay, thank you.

Similarly, can you give me the name of an article, a peer-reviewed published article, that talks about identification of degraded polypropylene by its ability to trap histological dyes?

MR. ORENT: Objection.

THE WITNESS: That is also my description.

BY MS. BYARD:

Q. Okay. You are the only one who has reported that finding, correct?

MR. ORENT: Objection.

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THE WITNESS: Specifically for polypropylene, yes, I'm the first one.

BY MS. BYARD:

Q. Let's talk a little bit about how specimens get to you from the surgical location, all right? In order to understand it and breakdown what you've said here in paragraph 6 a little bit better.

You would agree with me that all the specimens that you've reviewed were excised during surgery by a physician, right?

A. That's correct.

Q. And apart from what's described in the operative report of the excision, you don't know beyond that, what was done to remove the mesh, correct?

A. Specific details, no. The only thing I need to assess as a pathologist, is acceptable for examination and to what degree I can examine it.

Q. Okay. And my question is a little different.

My question is, beyond what's set forth in the op report describing this excision procedure, you don't know the details of what the

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surgeon did to remove that specimen, correct?

A. No, it's irrelevant to my practice. I don't ask it even if there were other regular diagnostic specimens.

Q. Okay. So the answer to my question is "no" --

MR. ORENT: Objection.

BY MS. BYARD:

Q. -- and you would also add that it's not relevant to you?

A. That's correct.

Q. Okay. And again, unless it's set forth in the operative report, you don't typically know what instruments the doctor used to excise this specimen, correct?

MR. ORENT: Objection.

THE WITNESS: I can deduct it from what I see. If I see cautery, then they used cautery. If I see depth of the changes in the tissue and so forth.

So, essentially, what I do, I go by what I see. And if something is different, then there are specific features to assess what happened to a specimen.

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BY MS. BYARD:
Q. For instance, are you able to discern whether the doctor used a scalpel or Metzenbaum scissors?
A. It doesn't matter to me. I mean, this is completely irrelevant.
Q. Okay. So the answer to my question is, no, you're not able to discern that, right?
A. No, I don't know why you're asking me this.
Q. Doctor, I just -- I just am asking you my questions. If you understand where they're coming from or not, is okay. But I just need answers so that we can move along, all right?
A. Okay.
Q. Okay. So the answer to my question is that you can't discern whether scalpel or scissors were used, for example?
MR. ORENT: Objection.
THE WITNESS: I can discern if it was hot or cold instrument.
BY MS. BYARD:
Q. Okay, thank you.
A. Or if it was crushing or sharp,

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that I can discern, but not beyond that.
Q. Thank you. And again, apart from what's set out in the operative report, you can't identify what degree of force, if any, was used to excise the specimen, correct?
MR. ORENT: Objection.
THE WITNESS: I can only define the degree of manipulation instrument or other handling affected it to a degree where I cannot assess if it's acceptable or not; that's what I can assess.
If the degree of manipulation was not strong enough to alter it in the way it would change microscopic appearance, then I cannot. But then it becomes irrelevant, because it doesn't affect my ability to interpret it.
BY MS. BYARD:
Q. And perhaps we can come back to that in reference to some of the specific cases tomorrow. But I'll move on for now.
On a similar line of questioning, you don't typically know, unless it's set forth in the operative report, what degree of difficulty the surgeon encountered in removing this specimen, correct?
A. Sometimes if it's really raggedy

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and piecemeal -- not necrose -- sorry, I'm a little bit.
If it's piecemealed resection and it's raggedy, it's clear that it was difficult excision. If it's cleanly excised, no damage to it, I mean, it's clear that it was easy excision.
Q. In the litigation context, you don't review the depositions of the excising surgeons, right?
A. No.
Q. You don't speak to the excising surgeons in the litigation context, do you?
A. No.
Q. Generally, though, you do know that doctors when excising specimens, need to grip the area of mesh that they're removing in order to accomplish the surgery, right?
A. Of course.
Q. And unless it's set forth in the operative report, you don't know what instrumentation was used to grip the mesh, correct?
A. No.
Q. Similarly, to the extent that distortions to the mesh occur as the doctor is cutting and removing it, you're not able to tell

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whether that distortion occurred in vivo, or whether it occurred during this removal process, correct?
A. That is not correct.
Q. For example, if you are given two specimens of mesh from a sling incision, you couldn't say that the mesh was broken apart in the women's body before it was removed, right?
A. This is not correct.
MR. ORENT: Objection.
THE WITNESS: Again, this is the second incorrect statement.
BY MS. BYARD:
Q. Is the way that you would tell, based on whether the -- both specimens are encapsulated in scar tissue?
A. There are multiple other features they can see. If damage was in the body, white cell reaction, I mean, including scar encapsulation, your guess was right.
Q. So after excision, the specimen is sent to pathology and put in a jar of formalin?
A. That's correct.
Um, not always. Sometimes I let it dry, so I had a few specimens which were left dry.

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Q. And I think you said the longest that you put your control sample of virgin mesh in a jar of formalin was four months?
A. Up to four months, yes.
Q. So from the operating room, the specimen goes to pathology at the patient's hospital or a local hospital typically, correct?
A. That's correct.
Um, if it is preserved, it goes to a lab through some channels. Some specimens are not preserved, they are discarded.
Q. If the sample or specimen is examined by a local pathologist, it's examined grossly and/or microscopically, typically, right?
A. There should be some form of examination, gross or microscopic; yes, that is correct.
Q. Okay. You talked about the sample being preserved; what does that process entail?
A. The main preservative is formalin, so it's kept in formalin.
Q. For the litigation context, you received samples through a company called Steelgate, right?
A. Most of the samples came through

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Steelgate, sometimes it comes from law firms directly or through Scisafe.
Q. Spell that for me.
A. I think it is Scisafe. S-C-I safe. My understanding is, it is a company similar to Steelgate.
Q. So someone has, either Steelgate or Scisafe of a Plaintiffs' firm, sent those specimens to you at this point in the process from the operating room to your lab?
MR. ORENT: Objection.
THE WITNESS: Most of the specimens come from either law firms or depositor like Steelgate.
Occasional specimens, when they are prospective, when the excision is planned, they come directly from the hospitals.
BY MS. BYARD:
Q. There is also a process of dehydration with increasing series of alcohol concentrations that are applied to the specimens, correct?
A. That's correct.
Q. Where does that process take place in these steps that we've outlined from the

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operating room to the laboratory?
A. After grossing. After I gross or somebody gross the specimen, they take sections, so it could fit in the cassettes. Then the cassettes are loaded in the machine, and then there's a process of dehydration, saturation of tissue with paraffin, and then the tissue can be cut when paraffin solidifies and then it can be cut.
Q. Sometimes that dehydration and alcohol application and saturation with paraffin process happens in your laboratory for these litigation specimens, but sometimes they happen at the local hospital?
A. That's correct.
Q. How long does the process of applying increasing alcohol concentrations take?
A. The machine can be programmed differently, but roughly it runs about, the full cycle is anywhere between 12 to 24 hours, with different solutions. The short --
Q. Is it just alcohol?
A. No, no. There are serial concentrations of alcohol increasing, and then xylene, and then xylene is replaced by paraffin.
MR. ORENT: "Saline"?

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BY MS. BYARD:
Q. X-Y-L-E-N-E?
A. That's correct.
Q. Then paraffin?
A. And all of those new meshes went through all the same steps, they were loaded in the same machine.
Q. You anticipated my question.
So the virgin mesh that you examined for degradation went through this alcohol dehydration?
A. (Witness nods.)
MR. ORENT: You have to say "yes".
THE WITNESS: Yes. Yes, sorry.
BY MS. BYARD:
Q. They went through xylene treatment?
A. They were loaded in the same rack, and the same basket as all other specimens, and then they went through exactly the same procedural steps.
And also, those specimens which had different thickness of the degradation layer, they also went through all the same. But, the correlation was only between in vivo exposure and

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thickness of the degradation layer; there was no correlation between the storage time. It showed 0 correlation. It was exactly like minus 0.06 or something like this.

While the correlation between in vivo and thickness of the bark was .76 which is very good for biological response.

Q. Is this data somewhere where I could look at it?

A. The publication is almost published. I mean, it's ready, it's written, so I need to just submit it. And, hopefully, when it is submitted soon, and it will be accepted, then I can present it to you.

Q. And until it's published, you wouldn't share that because it's considered confidential by you at this point --

A. Yes.

Q. -- is that fair?

A. Yes. At this point it would be, thoroughly.

Q. Once the paraffin processing takes place, the specimen is typically cut into a four-micron thick slice with what's called a --

A. Microtome.

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Q. Thank you. Sometimes for the specimens that you reviewed in litigation, those slices are made in your laboratory, but other times they've already been made by the local hospital; is that right?

A. That's correct.

Q. And then at some point in time during this process from the operating room to your laboratory, you apply stain, which you've talked to me about?

A. That's correct.

Q. Does that take place after you've prepared these four-micron thick slides?

A. Yes.

Q. And there is a staining called hemotoxin and Eosin, H&E?

A. Eosin, yes.

Q. Eosin?

A. Um-hum.

Q. That's one stain that you might use?

A. It's a basic standard stain, first stain. Most commonly used in North America as an initial stain. And most time it's the only stain which is used.

Q. You also performed staining with

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immunoperoxidase stains to do the S100 nerve observations?

A. Yes. Immunoperoxidase stain is technique for immunostains where antibodies labeled against specific proteins. And then you choose antibody against what protein you want to stain.

Q. You describe in your study with Dr. Carey, enzyme digestion for four minutes; what is that, for a lay person?

A. It's the way you try to reverse affect of formalin on tissue. So how formalin preserves tissue, it crosslinks proteins in a way that bacteria cannot degrade it anymore.

It's crosslinked, it ties up in a way that bacteria cannot digest it. But then some of the epitopes, it points where antibody is connecting, are hidden in this sort of crosslink.

So you have to un-crosslink, open it up. And for some antigens, it's -- it's enzymes -- usually, it is a protease, weakened protease.

Q. And that's only applied for four minutes?

A. It depends, I mean, these are tested -- sometimes manufacturer gives instructions, sometimes we have to adjust it. I

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mean, it's a quality assurance process. We use standard tissue to validate the stain and other things.

Q. For instance, you describe in your study with Dr. Carey that the enzyme or the retrieval process is something like 36 minutes for smooth muscle?

A. I mean, either manufacturer recommended that time, or we, in the lab, determined that this is optimal time for retrieval, antigen retrieval.

Q. You also in this process of staining the slide and using enzyme digestion to examine the slide, or really to prepare the slide for examination, you also incubate the slice?

A. "Incubate" means when you apply antibody, you need to give it time to work to find it; so this is incubation.

This time when you wait, apply antibody and wait until you can proceed to other steps.

Q. So for this process of dehydration and xylene replacement, and paraffin embedding and for enzyme digestion and incubation, are you applying heat?

A. 37 degrees, sometimes it's a

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little higher. I mean, there is a range of -- it depends on what retrieval is done and how it is done. But there is a degree of heating involved in some of the techniques.

Q. Celsius, 37 degrees celsius?

A. 37 degrees celsius, sorry. I completely forgot you're on a different scale.

Q. So as the specimen is undergoing paraffin embedding for 12 to 24 hours, it may be maintained at 37-degree celsius?

A. 37 or higher. I mean, depends. Sometimes there's no retrieval at all, it just stain it the way it is; without retrieval. So there is no temperature, and no, um, higher temperatures.

Q. If you were going to say that the specimens are subjected to heat up to a certain temperature, what would you -- what would be the "up to" amount?

A. 90 degrees centigrade, highest. I don't think it will go beyond in any of the steps.

Q. And where would you use those higher temperatures for processing?

A. Paraffin. Usually, the highest temperature would be melting point of a paraffin,

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maybe 80 degrees, maybe 90, I'm not sure now. Because I think if it's too high, the paraffin is brittle, it's melting point is high. If it's lower, it becomes too soft.

I would say probably closer to 80 than 90. But I'm not sure, I mean, it all depends.

Q. Were the samples of virgin mesh that you looked at for a control, and your degradation observations, subjected to 80 to 90 degrees celsius?

A. Yes. I mean, that's only way to embed it to melt paraffin. And, both the central non-degraded part was also exposed.

So I think there's internal control in each slide, non-degraded part is exposed to exactly the same procedural steps. There's no dying in the center, it remains clear. Therefore, all procedural steps have no effect on polypropylene degradation.

Q. My question was simply whether or not the samples were exposed to 80 to 90 degrees temperature, okay?

MR. ORENT: Objection.

THE WITNESS: Well, I mean, I just told you that both virgin tissue and the non-degraded

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parts were -- and degraded were exposed to exactly the same environment, heating chemicals.

BY MS. BYARD:

Q. And I'm not making a distinction between the degraded and -- the degraded bark as you've coined the term, and the non-degraded core.

I'm talking about the virgin samples of mesh, off the shelf, that you examined?

A. Virgin tissue was exposed to exactly the same temperatures and chemicals.

Q. I'm talking about virgin mesh.

A. Virgin mesh. Um, virgin mesh, sorry. Yes.

Q. It was, okay.

Did you expose the virgin mesh to all the same staining procedures that we've discussed?

A. H&E.

Q. Just H&E?

A. Yes.

Q. When you examine the mesh for the litigation cases for whether or not the sample absorbs dye, are you just using H&E stain?

A. I think it's incomplete question. To observe what?

Q. In paragraph 6 where you talk

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about the absorption of the mesh of histological dyes?

A. No. H&E and trichrome, and even immunoperoxidase, its counterstain was hematoxylin and it stains the degraded layer.

Any stain, any histological, histochemical stain, will stain it.

Q. So what I want to understand is, which dyes were applied to the virgin mesh, which stains --

A. H&E.

Q. -- were applied to the virgin mesh, and then which stains were applied to the mesh that you looked at for degradation?

A. For virgin mesh experiments, I used only H&E.

For specimens, and all pictures are there. I used H&E, trichrome stain, Gomori trichrome stain, Masson trichome stain, Von Kossa stain, immunohistochemical stains.

Q. So one difference between the virgin mesh samples, and the mesh samples that you examined for degradation that were surrounded by tissue, were the number of different stains that you applied to those specimens, fair?

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MR. ORENT: Objection.
THE WITNESS: Could you repeat the question?
BY MS. BYARD:
Q. Sure. So looking at specimens, mesh and tissue, you applied multiple different stains?
A. For some --
MR. ORENT: Objection.
THE WITNESS: -- specimens, I only had H&E. For some specimens I had more than H&E.
BY MS. BYARD:
Q. Okay. But for the virgin mesh samples you only used H&E?
MR. ORENT: Objection. Asked and answered.
THE WITNESS: That is correct. Because there are no purpose for other stains.
BY MS. BYARD:
Q. When you looked at mesh for degradation, you never cleaned the samples to remove the tissue, right?
A. No.
Q. As a pathologist, are there processes that you would use to remove tissue from

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a foreign body?
A. I don't understand the question, or are you reading from --
Q. I was asking. I was asking you, as a pathologist, are there processes that you would use if you wanted to remove tissue from a foreign body?
A. No, not really. Because we cut through specimens, so it would be totally separated.
Q. Okay. There's a way to do that if you wanted to, though, right?
A. I read an article, some researchers use separation to observe the surface, yes.
But we don't have to, because we slice across. For transmission electron microscopy, I got -- we're just cutting through it.
Q. Okay. It's possible that you haven't done it, because you didn't feel the need to do that?
MR. ORENT: Objection.
THE WITNESS: Not just didn't feel. It's not needed, period. For cross-sections it's not needed.

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Actually, you don't want tissue to be separated. You want tissue to hold the mesh.
BY MS. BYARD:
Q. Okay. You didn't remove tissue before you looked at the samples, and there is a way to do it?
MR. ORENT: Objection. Compound asked and answered.
THE WITNESS: Yes. That summarizes.
BY MS. BYARD:
Q. Okay. So when you're examining the mesh for degradation then in your report, you are looking at the mesh while it's still in the surrounding tissue, right?
A. Most of the time. Occasional filaments are kind of sticking out, or they are cross section -- like the slice of salami falls off.
Q. Okay. And in all the figures you've given us here in your report, all of the samples are embedded in tissue, right?
A. Yes.
Q. As I understand it, would these specimens that you receive, may have mesh that is oriented in the three-dimensional space of the

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specimen in different ways, right?
A. Yes.
Q. So when the knife of the microtome is cutting the specimen, you are not assured that the meshes that are completely perpendicular and angled to the knife blade, right?
A. What do you define as the plane of the mesh?
Q. So, mesh has a length, a fiber, and it has a width of fiber within its knitting structure, right?
A. You mean individual mesh fibers or -- well, it's more or less filaments. So fiber and filament in this case is the same term.
You mean individual filaments, if I know if they are entered perpendicular or obliquely? Of course I'd know. I mean, the shape, if it's perfect circle -- or close to perfect circle, it's close to perpendicular shape.
If it's oblique, then you have the long, longitudinal section. So for specific filaments, it's easier. Because you can see it.
For the whole mesh itself, it may not have a plane anymore, because it's all folded and it's -- there is no plane.

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Q. And the mesh might not be oriented in the specimen, along the length of the specimen, right?

A. Let's separate. Filaments, individual filaments and the mesh.

Q. That's what I was trying to do. You're the one who went to the mesh within the larger specimen potentially being folded.

Let's take out for now, just the fibers, the filaments of mesh itself?

A. That's okay.

Q. So because you don't know how the mesh is oriented in the specimen --

A. Mesh filament or the mesh?

Q. We'll get to that.

So because you don't know how the mesh, as a whole, is oriented in the specimen, you similarly don't know how the individual fibers are oriented in the specimen --

A. No, this is not correct.

Q. -- right?

A. I can go -- mesh filament is around the structure. So if it's cut perpendicular, there is a round cross section. If it is oblique, then you get an oval, and then

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sometimes you get a really long sort of cross section.

So just by the shape, I can tell you exact, approximately what's angle.

Q. Do you measure each one of the mesh shapes that you look at to assure that they are perfectly round?

A. There is a bunch of different shapes, and some of them are round, some of them are oval. So the more longer oval you get, the more angle -- I mean, more acute angle is.

Q. And so the way that you've represented mesh in your colorized figures is with yellow, right?

A. Yes.

Q. And many of those shapes, you'll concede, are not perfect circles, they're ovals; aren't they?

A. Yes. They are angled.

Q. And so when the knife of the microtome is cutting each specimen to create a slide, each mesh fiber or filament is not being cut at a 90-degree angle in every circumstance, correct?

A. That's correct. There is a degree

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of angle from 90 degrees to almost, um, almost parallel orientation, anywhere.

I mean, pretty much any specimen if it's large enough, you will find a range of angles.

Q. So not every slide is a 90-degree cross section of all of the mesh fibers contained in that section of the specimen?

A. That's correct.

MR. ORENT: Objection.

BY MS. BYARD:

Q. Does polarized light reflect off different thicknesses of material differently?

A. I'm not sure exactly what you're asking. If it brightens, it will be different if the thickness of the material is different? Yes.

If it's getting thicker, there will be more material, it will -- to a certain degree, I mean, that's to a certain degree I mean, so...

Q. It will get brighter or dimmer?

A. If it's clear, it will get -- to a certain degree, it will get brighter. When it's really thin, the brightness will be lower and then it will build up. And then after a certain thickness, it will not matter anymore. So it reaches full capacity.

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Q. Okay. So if I was looking at a thinner amount of material that was clear, under polarized light, it would be brighter or dimmer than thicker amounts of that same material?

A. If it's clear, because polarizable materials may be clear or not clear, so then there is a --

Q. It's clear in this hypothesis.

A. If it's clear, and it's really -- if it gets thicker -- I mean, start from very thin, barely visible. So the brightness of the light will be dimmer.

And then with increasing thickness, the brightness will be going up, up until it reaches full capacity. I mean, beyond which it cannot get any brighter. And then there might be some influence with light transmission and so forth there so...

Q. Okay. I think I understand, thank you.

A. But these sections I cut all at four microns. All tissue within the one section is exactly the same thickness.

Q. Not if it's not cut at a 90-degree angle, right?

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A. No, it's all four microns.
Q. If the material is oriented at an angle, and not completely 90 degrees --
A. It's still four microns.
Q. -- to the knife --
A. It's four microns. Can I draw it?
Q. It's a three-dimensional space, though.
A. No, it's a slice. So if you get slice like this, four microns. If you get slice like this, four microns. If you get slice like this, it's oblique, it's still four microns.
Q. But the way the material is angled within the specimen is tilted?
A. Yes. But it's still four microns thickness. The cross section is four microns thick, it doesn't matter what orientation, it's still four microns. Doesn't matter how you're in it, four microns. It's like a salami.
Q. But if you look at it from looking up, you would be looking through less material on the far edge of the material if it was oriented sideways?
A. Or the very edge, the very tip of this, yes. It will be somewhat different, yes.

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Q. Okay, thank you. Thank you.
THE VIDEOGRAPHER: Excuse me, Counsel. I have to change the tape.
MS. BYARD: Perfect, let's take a break.
THE VIDEOGRAPHER: This marks the end of media number three in the deposition of Dr. Vladimir Iakovlev.
We are going off the record at 5:28 p.m.
-- RECESS AT 5:28 --
-- UPON RESUMING AT 5:38 --
THE VIDEOGRAPHER: Here begins media number four in the deposition of Dr. Vladimir Iakovlev.
We're back on the record at 5:38 p.m.
BY MS. BYARD:
Q. Doctor, I have some relatively straightforward questions about the figures in your report related to paragraph 6. If you wouldn't mind turning with me to Figure 9C.
A. What page number?
Q. It's on page 33, sir. And I guess, really, this question refers to 9, 9A, 9B, 9C, really all the way through to 16.

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And in none of these figures do we see the entire circumference of the mesh filament, do we?
A. No, because it doesn't fit. Well, the thickness of this degraded layer is anywhere between two to six microns. Filament is up to here. It wouldn't fit.
Q. Okay. So in the -- at the level of magnification that you need to view this narrow margin, what you call the degraded bark, you're not able to capture the entire circumference of the mesh filament in your imaging?
A. Yes. This magnification size of filament is much larger, several pages larger. In some lower magnification, you can still see the degraded layer, but it's much less details.
Q. One question I had was how you're able to tell that there isn't tissue interposed over the edge of the filament, and your eye, through the microscope.
So if you're able to answer that, if not I can rephrase.
A. How do I see if there's no tissue overlapping with the filament? Sometimes it is, just play with focus. Because it goes like this.

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It's a different plane of focus, so you cannot focus on exactly the same. Even within four microns, you can focus only within very narrow range.
So, essentially, you're looking at the slice which is much thinner than four microns. Probably you'll be in the focus of a range of one micron thickness only. The rest will be blurred.
Like this picture, you mentioned 32. You see this is completely blurred. And it's probably just one micron deeper than this part. It's different plane, and it's out of focus, and then you don't see any details. Little further down, it will be just pink haze, from the breakoff.
Q. Okay. So in order to focus in on what you call the degraded bark, you have to focus in at a level where you are assured you're looking past the tissue?
A. What do you mean, where it overlaps?
Q. (Nods.)
A. Yes. I mean, I can even see -- I can focus on different layers of degraded material. On deeper, some more superficial, because focusing depth is very narrow. As I said, within one micron -- with that magnification, it's very shallow.

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Q. You would agree, though, that it is typical for there to be some tissue overlapping the circumference of the mesh filament on cross section?

A. No. Typical is contraction, so tissue contracts during dehydration, it splits and goes away. Usually, the way when it overlaps, when it lifts up, floats and sits on tissue.

But if it sits in situ, this should contract and retracts. So usually there is a separation. Sometimes there is not on edges, but overlap with the tissue is least common phenomena.

Again, any overlap in the field will not be visible because of the depth of sharpness. I can focus on the very narrow depth. You can have 15-microns difference with different layers, and if you have enough light which is passing through, you can gradually see layer by layer, and steady details within these 15 microns.

Q. Have you continued soaking that virgin mesh or other virgin mesh samples in formalin?

A. Yeah, I have some still sitting in formalin.

Q. When was the last time that you

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examined them for degradation?

A. Sometime during summer. But sometimes I completely use up the sample, so I have to start the process again, so it's not -- the first mesh was exposed, I think last fall. But I don't think I have samples from that time, so there will be -- I just have dates written on the jars, so...

Q. Okay. And the longest still it's been in formalin is four months?

A. Four months. It's way beyond the -- when I was writing this manuscript, we talk about, about 25 percent of the samples had exposure time less than a month. And about 8 or 10 percent of the specimens I examined had exposure to formalin less than 72 hours. And they still showed the same degradation layer, so...

Q. And you're referring to one of your published studies?

A. In preparation. But I'm just telling you the date. So four months is overkill by many fold.

Q. Okay. And that's not data that we have yet, right?

MR. ORENT: Objection.

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THE WITNESS: I'm telling you.

BY MS. BYARD:

Q. You're telling me, but I don't have the underlying data, right?

MR. ORENT: Objection.

THE WITNESS: That's correct.

BY MS. BYARD:

Q. Okay. Looking at paragraph 7 of your report, sir, on page 6. You write that:

"The published literature indicates that the main complications of transvaginal mesh devices leading to mesh excision are chronic pelvic pain, pain with intercourse, parenthesis, [dyspareunia], de novo, worsening urinary symptoms and mucosal erosion, parenthesis, [mesh exposure]."

Which articles are you relying on for that statement?

A. Clinical.

Q. Are there articles in your list of materials reviewed that you can point me to for that proposition?

A. The regular complications? Yes.

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I mean, there are some clinical articles there.

Q. Any in particular that you would cite for support for that proposition?

A. I would have to check these papers again, sorry. Because it's been quite sometime. I don't remember exactly which article specifies, but...

Q. Now in contrast, your data that you publish with Dr. Carey indicated that the number one reason for excision in the samples that you reviewed there, were for exposure, correct?

A. You mean mucosal exposure? Yes.

Q. Okay. If I were to ask you what the rate in the medical and scientific literature of excision for dyspareunia was, compared to the rate of excision for dyspareunia in your 120 specimens, you couldn't cite me those numbers, could you?

A. I would have to go through papers and -- the rate will be different in each paper, and there is no such thing as the same rates. So there will be a range of rates.

Q. And that analysis hasn't been completed, has it?

MR. ORENT: Objection.

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THE WITNESS: What do you mean, which analysis?
BY MS. BYARD:
Q. Comparing the range of reported rates of dyspareunia as the reason for excision in the published literature, with the rate of excision for dyspareunia in your sample size of 120 specimens?
A. If I published this comparison? No, I have not published this comparison.
Q. And you haven't done that comparison yet, either, right?
A. Well, roughly I estimated. Because you can see in the papers what is percentage of those excised for -- where is it?
Q. It was Exhibit 1198.
A. So if we split now, see I have -- I had 67 percent exposure, 56 percent pain, and overlap between them, 33 percent.
Q. That was for 24 specimens, though?
A. Yeah, that was a pool size in that. If you're asking for complete set, no. And this set is growing every day, I mean I'm receiving samples, so...
Q. So for the set of 120 specimens,

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you can't tell me what the rate of complications were prompting the revision surgery, right?
MR. ORENT: Objection.
THE WITNESS: I can estimate the range anywhere from 30 to 50 percent, somewhere. It depends on the -- I mean, again...
BY MS. BYARD:
Q. You don't have those numbers or those statistics analyzed yet, correct?
A. Not for the total number of specimens I received by today. I mean, I initially, as for this study, I did analysis; and then I think I did analysis sometime in between. But I mean, I have not done it like yesterday --
Q. Okay.
A. -- for all specimens I receive.
Q. The numbers you can quote for me today are from these 24 samples that are -- that have been analyzed in the study that you published with Dr. Carey that's Exhibit 1198?
A. This is just the paper in front of me. I might have the number on the spreadsheet in my log of specimens.
Q. Okay. And they're not set forth in your report, right?

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A. No, but --
Q. Okay, thank you.
You write here in paragraph 7, that this is consistent with random sampling since the samples had variable sources and manufacturers; do you see that?
A. Yes, they were coming from different sources, from -- they were of different manufacturers. They were excised for different reasons. The range of patient demographics was large.
Q. You haven't set up a registry, though, for mesh excisions in the transvaginal mesh example like you have for hernia mesh in your study with Dr. Bendavid, right?
A. No. Those samples are obtained prospectively, these samples were obtained retrospectively.
Q. And the sources were threefold. They were either St. Michael's, they were other hospitals, and they were from the Plaintiffs' lawyers through various --
A. But when they come from lawyers, they're not coming from one specific individual. They're coming from different excising surgeons,

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different states, different hospitals of -- you make it sound as if lawyers, just one person, one clinician and one lab, no. It's all over, you know that.
Q. And your research on hernia repair mesh, you didn't receive samples from Plaintiffs' lawyers, right?
MR. ORENT: Objection.
THE WITNESS: Which research?
BY MS. BYARD:
Q. The study that you published with Dr. Bendavid?
A. The SIN paper? No, there was no litigation cases in this paper.
Q. Paragraph 8 continues:
"Pain is reported as the most frequent complication of a mesh procedure in published literature and in the clinical records that I reviewed."
Do you see that?
A. That's correct.
Q. Which study are you relying on for that proposition?
A. There were a number of studies

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where the pain was higher. Sometimes there are other -- pain is a very subjective subject, and sometimes it's not assessed. There is no primary goal of the studies to assess pain, so they just provide statistics. When the study is more focused on pain, the numbers might be higher. So it's a range.

Q. And the studies that you reviewed, what was the range of reported pain as a reason for excision?

A. You mean percentage-wise? I don't remember now, but I mean there were a number of studies which showed pain as a first -- the number was higher, higher than anything else.

Q. Are you referring to hernia mesh literature or transvaginal mesh literature?

A. Transvaginal mesh. And this is just complication, it's not a reason for excision.

You see, if you read this, "the pain is the most frequent complication." So if you go through it, it may go up to 30 percent, even higher in some literature. Some literature it goes -- in some publications it goes lower.

Q. As you were reviewing the medical literature on complications of transvaginal mesh,

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did you keep any notes on what the reported rate of complication was for different symptoms?

A. No. Because I wasn't writing a paper for that specific, it was just a memory of my understanding.

Q. Do you agree that innervated tissue, anywhere in the body, can be subject to potential pain mechanisms of direct irritation to the nerves?

A. Yes.

Q. Entrapment?

A. Entrapment in normal tissue?

Q. (Nods.)

A. If entrapment happens, it's abnormal. I mean, if you assume that there are places in the body which can cause entrapment syndromes, the entrapment itself becomes abnormal.

Q. Sure. And I'm talking about innervated tissue anywhere in the body can present a finding of entrapment on histological examination?

A. No, it cannot. Entrapment, in normal circumstances, occurs in tight spaces where nerves pass by. So these are very specific anatomical locations.

Q. It's possible for nerves to be

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entrapped in tissue that was never exposed to mesh, right?

A. No, this is not correct. If you take tissue as a general, there cannot be entrapment because there is no tight area. Entrapment happens in specific anatomical locations where there is a tunnel, or there is a compartment. I'm talking about normal, spontaneously occurring sort of entrapment or tunnel syndromes.

This is not happening in, in tissue as we talk about it. It's like a tunnel, usually surrounded by some kind of winding, synovial winding of the place, tight spot where nerves pass through.

Q. So if I understand your testimony correctly, you can have nerve entrapment in the body, even if there's not any mesh, against certain anatomical structures, or tunnels, or compartments as you've described it?

MR. ORENT: Objection.

THE WITNESS: I mean, usually there is some degree of pathology called changes in the area. It's not normal to have an entrapment syndrome.

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BY MS. BYARD:

Q. Sure. But what I want to focus on here are abnormal pathological findings that are mechanisms for pain.

And I want to focus on abnormal pathological findings that are mechanisms for pain, and whether those mechanisms exist without mesh?

A. In the vaginal area, no. There are no anatomical locations, or specific anatomical structures to cause nerve entrapment without mesh.

Q. Without mesh you can never have nerve entrapment in the vagina; is that your testimony?

MR. ORENT: Objection.

THE WITNESS: If there is no mesh and there is no other pathological condition, like a tumor or something else, it cannot happen.

BY MS. BYARD:

Q. Okay. So if there is a tumor you can have nerve entrapment?

A. That's correct. With tumor, there will be little bit different mechanisms. But there will be effected nerves.

Q. Okay. If there's another foreign body besides the mesh in the vagina, there could be

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nerve entrapment?
A. If there is foreign body with compartment.
Q. Okay. Innervated tissue anywhere in the body can be exposed to pain mechanisms that are inflammatory in nature, right?
A. Spontaneously occurring inflammatory conditions, that's what you mean?
Q. Any sort of inflammatory mechanism of pain.
MR. ORENT: Objection. Vague.
THE WITNESS: As we stated before, as I stated before, inflammation alters sensitivity threshold.
So any inflammation can build up, so the basis for pain, or cause pain if it's sufficiently high enough.
BY MS. BYARD:
Q. Can compression by edema act as a mechanism for pain for tissue with nerve ingrowth, even when there is no mesh present?
A. If it's enclosed compartment -- well, see, edema, if there's no walls of a compartment, edema will expand further. If it grows rapidly, it may cause some discomfort or

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pain. If there is no compartment, edema will -- and if it goes slowly, it will just be painless edema. But the problems are when the edema goes faster; or, if it occurs in enclosed space.
So you need to set some pathological condition. To form this walls of compartment, or place foreign body, and then, to cause edema. And then edema would occur in an enclosed compartment.
Q. So in certain pathological conditions, in the absence of mesh, compression by edema can cause pain?
MR. ORENT: Objection.
THE WITNESS: That's correct.
BY MS. BYARD:
Q. Even in the absence of mesh?
A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling.
Q. Thank you.
Is the same true for ischemia?
MR. ORENT: Objection.
THE WITNESS: For ischemia, yes. Again, that's why I can state that this has probability to cause pain, because we know that it causes pain in other parts of the body.

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BY MS. BYARD:
Q. That's a very fair point. The entire reason you have identified these potential pain mechanisms with mesh, is because these are well understood mechanisms for pain in the literature, apart from any findings related to mesh, correct?
A. Yes. But, when I examine specimens, I don't find anything else except for changes related to the mesh. I don't find the tumor, I don't find musculitis, which can cause necrosis of the vessels.
So, part of my job as a pathologist, is to rule out other conditions. And then I see only changes which are related to the mesh.
Q. As a part of your practice, though, in the litigation context, if you receive a specimen that's a uterus, and clearly not mesh, you don't examine it?
A. I do examine it.
Q. You do?
A. I do, yeah. If I receive a specimen, I look through the microscope.
Q. And do those findings make their way into a report that's disclosed to us?

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MR. ORENT: Objection.
THE WITNESS: I don't remember now.
BY MS. BYARD:
Q. Withdrawn.
In the absence of mesh, there can also be mechanical irritation of receptors, right?
A. Mechanical, if it's normal degree of stimulation, it will not cause pain. If it's abnormal degree, if it's high enough, it will cause pain. That's how --
Q. Yes. Exactly.
A. -- take a hammer and then it will, it will hurt without mesh.
Q. Okay.
A. But if you just press it with your finger, just feel the touch.
Q. Ending paragraph 8 you write:
"These findings correlate with clinical findings of pain, particularly chronic pain in women."
Do you see that?
A. Yes.
Q. What's the difference, in your understanding, your vocabulary, between "correlation" and "causation"?

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A. Clinical pathological correlation. So when I receive a specimen, and described as removed for reasons of pain, as I said, I examine it for pathological findings, I rule out natural occurring non-mesh-related conditions, then examine what happened in the mesh. So, that's what it meant.

Q. Okay. And so it's not as if you're looking at a pathological -- a pathology slide and saying, "aha, it was this edema that caused all this pain that she reported." Right?

MR. ORENT: Objection.

THE WITNESS: See, when I receive a specimen, I know that there was pain, and it's indicated that -- sometimes I look at the history later. So I know that there was pain, and I do clinical pathology called correlation.

You cannot -- it's not a game, I mean, it's a diagnostic process. You have to take all information available to you and then correlate.

Clinical investigation was done because of pain, they narrowed down problem to the excised mesh, I received a specimen. So I already know that there was a problem, complication, that's why it was excised.

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Then I try to figure out what was causing it, what is abnormal in the specimen which was removed as a part of treatment of the complications, or patient's symptoms. And then I rule out naturally occurring, I don't see it, and then I see this.

And then, if somebody tells me, "I have a pain." And I examine the specimen, and there is mesh with edema, with nerve ingrowth, this is the cause of pain. Because there is nothing else in the specimen which would explain it.

BY MS. BYARD:

Q. Now, if that patient's pain continues after that mesh is excised, you can then agree with me that the edema, or the foreign body inflammation can no longer be considered the cause of those symptoms, right?

MR. ORENT: Objection.

THE WITNESS: If entire mesh is excised without damage to the tissue, which is hypothetical, I don't think most of the meshes can be excised completely, or completeness of excision can be as certain. So the first difficult part of the statement.

The second difficulty is that when you

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excise, you cause damage, and there is more scarring. Because when you do multiple procedures throughout, the scar is there. So there might be some residual changes in there. So the initial cause of these changes would be still mesh.

How do you separate all of this? And how do you ascertain completeness of excision? How they are certain that the postexcision changes are not residual changes which occurred while mesh was there? This is difficult.

BY MS. BYARD:

Q. You would agree that correlation isn't causation, though, wouldn't you?

MR. ORENT: Objection.

THE WITNESS: See, when you use causation, do you use it in -- let me ask, I mean, just to clarify this.

When you use word "causation," do you mean "prediction"? Or correlation of clinical picture with the pathological findings?

BY MS. BYARD:

Q. I guess maybe the better way to ask it is that the word you used here was "correlate," right? Not "cause"?

A. And I explain it. Correlation is

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clinical pathology calculation. Patient comes with complication, symptoms. So that's where clinical part comes in. And there's investigation, there's narrowing down, and then I examine the specimen to see what is abnormal in it. So this is diagnostic process and treatment process.

If you're talking about prediction, what can happen in the future is something occurring now, that's not how medicine works.

So the correlation here, correlation between what was clinically seen abnormal, and what I see in the microscope.

Q. So you're relying, in large part then, on the clinical determination that's made by the treating physician, that the doctor and the patient should at least try to excise the mesh to address the patient's symptoms, right?

A. Yes.

Q. You also write that:

"Placement of vaginal tissue --" and I'm looking at paragraph 9 now, Doctor. "-- is associated with a higher risk of chronic pain issues than the placement of abdominal mesh -- abdominal hernia mesh." Excuse me.

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A. That's correct.
Q. And what literature are you citing for that proposition?
A. Again, clinical literature. Being in the hernia is lower, somewhere in the range from about 10 percent or so, but for transvaginal meshes it can go up to 30 percent.
Again, it's very, very difficult to compare the studies, because they use different questionnaires and different approaches.
Q. And are you talking about rates of chronic pain as a complication overall, or is it complication leading to excision in this statement?
A. Complication overall.
Q. We talked earlier about how the vagina compared to the abdominal wall, as a nerve-rich environment, right?
A. Yes.
Q. And you would also agree with me then, that the vagina as an area of the body is associated with a higher risk of chronic pain compared to the abdomen, because it is a more nerve-rich environment, right?
A. Yes.
Q. And that's true in the absence of

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mesh, too, isn't it?
A. Yes.
Q. You conclude paragraph 10, with the statement that:
"It is well established that inflamed tissue alters the sensitivity threshold of pain receptors."
A. Yes.
Q. Are you with me?
A. Yes.
Q. Is there a specific study or studies that you're relying on in support of that proposition?
A. There are studies, I mean, but you probably experience inflammation yourself during your lifetime, everybody does. So do you need a study to learn this?
Q. Leave me out of it. Let's leave me out of it.
Is there, so you can point me to, though?
A. I mean, everybody experience inflammation in their lifetime. Everybody knows. And there are studies which are studying mechanisms of that. The fact itself is not even commonsense,

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it's personal experience of each individual.
But the studies who studied further, how it happens with inflammatory mediators and other things, yeah, they are there.
Q. There are studies that exist?
A. There should be at least in that.
Q. Okay. Are there studies looking more specifically at inflammation and foreign body reaction in the presence of mesh, and whether that heightens the sensitivity threshold of pain receptors?
A. It's almost like narrowing down something to a specific area, like could there be a doctor for a little right finger.
Q. The answer is, "no," right?
A. There are studies which study inflammation, in general. I mean, there's a physician or any thinking person, you can apply it to any areas so...
Q. So the answer to my question is, no, the literature doesn't get that specific, right?
MR. ORENT: Objection.
THE WITNESS: Not that narrow.

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BY MS. BYARD:
Q. Thank you. Let's look at page 8, please.
I assume your response will be the same, but with respect to transvaginal mesh, or really just polypropylene mesh in general, you can't point me to a specific study showing that the pain caused by swelling is present in amplified state, because of the compartments of mesh, right?
MR. ORENT: Objection.
THE WITNESS: Specific studies? I mean, we described it in our paper. But specifically that the edema was studied in meshes, I cannot -- there are no studies which specifically studied edema in meshes.
BY MS. BYARD:
Q. And you would concede that there could be women with edema present in the presence of their mesh, who don't complain of pain, right?
A. It's possible that there is edema within some compartments, and it doesn't cause pain. Because it's a complex process, you might need several factors which play together to cause pain. Some people not sensitive, some people don't complain, so this is not black and white.

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Q. Okay. And the same thing is true for scar tissue, right? We know that all mesh will be present with scar tissue, and yet not all women with mesh experience pain?

MR. ORENT: Objection.

THE WITNESS: See, this is difficult. Because I don't actually have the specimens from women who for sure didn't experience pain, or didn't experience any complications. This would be an autopsy series, which is difficult.

So all cases I receive, they have complications, all have scars. If those who never have any complications, how much of scarring -- there would be scar, if there is a different extent of scarring, I don't know.

BY MS. BYARD:

Q. In fact, let me rephrase that. Strike that.

The fact that women can have scarring because of mesh, but not experience pain, tends to call into question, the association between the presence of that scar tissue around the mesh and pain, doesn't it?

A. It contributes. The scar itself, wouldn't be a problem. But scar with mesh, with

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innervation, with connection to other areas, then the whole complex of changes, this leads to pain.

Q. Well, from your research you've concluded that all mesh will have innervation, right?

A. Transvaginal?

Q. (Nods).

A. Yes. Because all meshes I received. But again, I don't know what is happening in those meshes which don't have any complications, or patients don't complain to a degree that the mesh is excised.

Q. Okay, thank you.

Have you heard of a condition called pelvic floor congestion syndrome?

A. Not specifically.

Q. Do you know if there are ways to measure blood flow in the pelvis?

A. Dopplar.

Q. And you haven't looked at studies on that issue, have you?

A. On Dopplar studies, no.

Q. Would you agree with me that blood vessels can become dilated and congested in the vagina and surrounding area in the absence of mesh?

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A. Possibly in some locations, yes. But when I see it in the meshes, everything outside of mesh is collapsed, and then vessels in the folds of the mesh are dilated.

So, therefore, I have internal control. I see what is outside of the mesh and I see what is inside of the mesh, it's different.

Q. You've looked at about 120 specimens of transvaginal mesh at the time that you authored your report.

Do you have any statistics that you can cite for me for the rate of dilated and congested vessels in non-scarred vaginal tissue that you have examined in your course as a pathologist.

A. See, normally, you don't see congestion. Congestion of the vessels is not normal. I mean, there has to be something which is causing it. So if it's normal tissue -- if I quote it "normal," it means that there are no pathological findings.

If I see congestion, and some other changes, I mean, this would not be perfectly abnormal. I mean, there might be some bleeding due to surgery or something else.

Q. You can't quote a rate then

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because you don't see it typically; is that what you're saying?

A. What do you mean, rate of what happens with --

Q. How often those findings are present in non-mesh vaginal specimens?

A. I don't see it.

MR. ORENT: Objection.

THE WITNESS: I don't see it normally.

BY MS. BYARD:

Q. And I'm using the word "normally" to describe "commonly". I'm asking about abnormal pathological findings.

A. I don't understand exactly. If you want me to tell if I see the difference what is inside the mesh of tissue, and what is outside on the mesh, either in the specimen of mesh or specimens without the mesh; there is a marked difference between what is inside the mesh and outside the mesh.

Q. And I'm thinking about patients who undergo excisions who have never had mesh. Not variation within a specimen.

MR. ORENT: Objection.

THE WITNESS: I don't see any

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congestion. If it's a healthy, elective procedure for hysterectomy, when they do some trimming of the vagina, and then they get vaginal cuff, there is no congestion.

BY MS. BYARD:

Q. Okay.

A. No edema, no congestion, no inflammation, is pristine tissue.

Q. And that's for a patient who's undergoing surgery electively, not because the uterus or surrounding organs, the ovaries, were identified as being a potential cause of that woman's complaints, right?

A. There are complaints. I mean, there is a reason for hysterectomy. Usually it's dysmenorrhea or just --

Q. Heaviness?

A. Excessive bleeding in perimenopausal periods, so they don't want to have -- to take drugs, so...

Q. Okay. You write in paragraph 13 about muscle relationships with mesh; are you with me?

A. Yes.

Q. Can striated muscle grow within

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the mesh structure?

A. That's a difficult question. Technically, muscle itself cannot grow through the -- or in large amount, cannot grow through mesh.

So there has to be a combination of either mesh placement into the muscle, which is done, we know. Or migration of the mesh into the muscle, and a degree of muscle regeneration in the folds or in the -- so it would be a combination of factors, how the mesh -- how the muscle strands become inside the mesh pores or folds.

Q. And you can't say when you look at a specimen, how that muscle and mesh got to where they are?

A. Depends. In some specimens, the mesh just cuts through the muscle, and you see the trail of the muscle, it just sifts through it. Then I can say for sure the mesh migrated into the muscle, it left behind. But now muscle is interrupt, because mesh just went through it. But sometimes it's an array of different things, so I don't know, I cannot tell.

Q. You write that:

"Where muscle is attached to

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mesh, muscle contraction results in pulling of the entire mesh."

Do you see that?

A. Yes.

Q. Can you point me to any published articles that show muscle contraction pulling on the mesh?

A. No, it has not been specifically studied in that specific sequence as you word it.

Q. You could design an experiment where you could look at muscle contraction in its relationship to mesh, couldn't you?

A. What I do see, when I can tell you that if the muscle strength is viable, so it's contractile. Because see, with a muscle, if it doesn't -- if it degenerates, it's not contract anymore.

If it's healthy muscle, it will contract. So those muscle fibers or bundles, I see in the mesh, they're healthy. Therefore, they contract.

Q. As far as how the mesh is then pulled by that muscle contraction, you could design an experiment, though, looking at, for instance, 3D ultrasound technology?

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A. Oh, if the mesh is moving during movements, and -- yeah, you can do it. I mean, you can see -- well, as long as mesh is mobile. If it's so tight that it's not mobile anymore, like if it's saw it here in between pubic bones, then it will not be mobile. But it doesn't allow -- that muscle is trying to contract, it just cannot move it anymore because it's so immobile.

Q. And you're talking about various scenarios that you could understand based on your training and experience, correct?

A. That's correct.

Q. You're not talking about findings that you've seen based on an experiment using, for instance, 3D ultrasound technology that you, yourself, have performed, right?

A. No. I'm basing what I see on the microscope. If it's healthy muscle, within the mesh, completely surrounded by the mesh, it's contraction will cause movement of the muscle.

Q. And you haven't tested your hypothesis about how muscle contraction will interact with mesh in living patients?

MR. ORENT: Objection.

THE WITNESS: It's not a hypothesis.

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This is my interpretation of the microscopic findings, that's what I'm trained to do. Interpret what I see in the microscope, so...

BY MS. BYARD:

Q. You haven't tested that finding in living patients, right?

MR. ORENT: I'm not sure if he was done with his prior answer.

BY MS. BYARD:

Q. Oh, sorry.

A. See, this is not my job, I mean, I know what tissue does. So if a muscle is healthy, it contracts. This is what we know based on -- mesh, no mesh, we've known it for thousands of years, muscle contracts. If it's healthy muscle, it contracts. If it is in the mesh and completely surrounded by the mesh, the contraction will pull. So this is my interpretation as a pathologist.

If I measured what the strength, what the force it produces in that specific section, no, but I don't have to. Because my job is interpretation, and that is my interpretation.

Q. Okay. So in answering my question, have you tested this yourself in humans, in living humans, your answer would be, "no"?

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MR. ORENT: Objection.

THE WITNESS: No. I mean, I explained to you that I interpret based on what we know about tissue reaction and general physiology of humans.

BY MS. BYARD:

Q. Okay. You also write that:

"Mesh in smooth muscle can interfere with muscle contraction and organ function."

A. Yes.

Q. Again, you haven't used any imaging to test in human beings, how mesh present with smooth muscle interferes with muscle contraction or with organ function, have you?

A. I'm not radiologist, I don't use images -- what I see, I see when the mesh is in the smooth muscle, I know it went all the way to urinary bladder, it's somewhere in the detrusor muscle. I mean, if the bundles are consistent with bladder. It correlates almost 100 percent with clinical descriptions of urinary symptoms.

Q. So in answer to my question, no, you haven't studied that in humans because you're not a radiologist and that's not in your area of study --

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MR. ORENT: Objection.

BY MS. BYARD:

Q. -- right?

A. That's correct.

Q. There are ways to measure the forces at work in the body, aren't there?

A. You have to explain a little bit more, what do you mean "forces in ways --"?

Q. Well, there are ways that you could measure, for instance, the intraabdominal force placed on muscle through, through ultrasound technology, can't you?

MR. ORENT: Objection. Vague.

THE WITNESS: I'm not sure if you can use ultrasound to measure the force.

For diagnostic purposes, I don't -- well, I mean, first of all, I'm not sure if it can be done. Second, I don't see diagnostic purpose, and I certainly wouldn't expect it to be done for diagnostic purposes.

BY MS. BYARD:

Q. Are you familiar with something called "urodynamic testing"?

A. Urodynamic is different.

Q. How so?

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A. Well, then they measure forces and pressures to understand what's causing urinary symptoms.

Q. And they measure the forces of various intraabdominal contractions, or the detrusor muscle contraction --

A. Detrusor muscle, yes.

Q. -- within the female body, right?

A. Yes, there is --

Q. That's not an area that you've studied though, correct?

A. No. No, I have not.

MR. ORENT: Counsel, we're at 6:25, we're going to wrap up in about five minutes.

MS. BYARD: Okay. I might be at a good stopping point then.

BY MS. BYARD:

Q. There's also a discussion here of limited elasticity. And, similarly, there are ways to study the elasticity of different tissues within the body, aren't there?

A. Yes, including gross examination, which I do.

Q. But there is testing that can be done beyond gross examination, right?

A. For my purposes, we are not doing more than that as a pathologist. If it's done for any other diagnostic procedures, I'm not aware of commonly used diagnostic tool which would use elasticity for a specific diagnosis.

Q. Well, researchers have looked at the elasticity of virgin tissue compared to scar tissue, haven't they?

A. Well, that's research. Research and clinical practice are different areas, I mean --

Q. So irrespective of whether it's in research or clinical practice, there are ways to look at the relative elasticity of different types of tissues?

MR. ORENT: Objection.

BY MS. BYARD:

Q. True?

A. Yes. I mean, mostly for research, as I expect. Maybe there is a very limited amount of clinical applications, like for genetic conditions when there is not enough collagen or something else, I mean, but --

Q. Or with pelvic organ prolapse, too, where there are different types of collagen

present at different levels that lead to abnormalities in the structures of the pelvis?

A. I don't think it is not. Pelvic organ prolapse is just by visual assessment and degree of prolapse.

Q. Do you know how the presence of different types of collagen in the pelvic floor correlate to incidence of pelvic organ prolapse in women?

MR. ORENT: Objection.

THE WITNESS: Collagen alteration, the ratios, I mean, they affect not just pelvic organ prolapse, they affect the whole body. There will be abnormalities, aortic dilatation and hyperelasticity of joints and so forth. So it's not just pelvic organs which are affected.

BY MS. BYARD:

Q. But that's not an area of your study, right?

A. But this would be an abnormal genetic condition, if we talk about collagen alteration.

If it's a normal, healthy person, I mean, there would not be collagen alterations beyond what is normal expected with aging.

Q. Well, in a normal healthy person, you wouldn't see pelvic organ prolapse to begin with, would you? That's an abnormal finding?

MR. ORENT: Objection.

THE WITNESS: Partially, it's a relaxation, age-related; so what do you mean? I mean, healthy younger individual, yes, this would be a problem.

BY MS. BYARD:

Q. Similarly, stress urinary incontinence is an abnormal finding, isn't it?

A. Yes.

MS. BYARD: Okay, Doctor, I think we've reached a good stopping point for the night. I thank you for your time.

THE WITNESS: Thank you.

THE VIDEOGRAPHER: This marks the end of media number four in today's proceedings in the deposition of Dr. Vladimir Iakovlev.

We are going off the record at 6:31 p.m.

-- Whereupon the deposition was suspended at 6:31 p.m.

REPORTER'S CERTIFICATE

I, JUDITH M. CAPUTO, RPR, CSR, CRR, Registered Professional Reporter, certify;

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed;

That the foregoing is a true and correct transcript of my shorthand notes so taken.

Dated this 23rd day of December, 2014.

_____

PER: JUDITH CAPUTO, RPR, CSR, CRR

CERTIFICATE OF REPORTER

CANADA)
PROVINCE OF ONTARIO)

I, Judith M. Caputo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand, using Computer Aided Realtime, to the best of my ability and thereafter reduced to written format under my direction; that I am neither counsel for, related to, nor employed by any of the parties to the action in which the deposition was taken, and further that I am not related or any employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.

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Judith M. Caputo, RPR, CSR, CRR

Commissioner for taking
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NAME OF CASE: IN RE: BOSTON SCIENTIFIC CORP., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION
MDL NO. 2326
DATE OF DEPOSITION: DECEMBER 17, 2014
NAME OF WITNESS: VLADIMIR IAKOVLEV, M.D.

PAGE	LINE	FROM	TO

_____
VLADIMIR IAKOVLEV, M.D.

PROVINCE OF ONTARIO)
TORONTO REGION)

I, the undersigned, declare under penalty of perjury that I have read the foregoing transcript, and I have made any corrections, additions or deletions that I was desirous of making;

That the foregoing is a true and correct transcript of my testimony contained therein.

_____
VLADIMIR IAKOVLEV, M.D.

Subscribed and sworn to before me this ____
Day of _____, 2014 at
_____, _____.
(City) (Province)

_____
(Notary Public)
My Commission Expires: _____